

89-1528

Supreme Court, U.S.

FILED

MAR 14 1990

STEFAN F. SPANIOLO, JR.
CLERK

IN THE

Supreme Court of the United States

OCTOBER TERM, 1989

COX-UPHOFF CORPORATION and
COX-UPHOFF INTERNATIONAL,

Petitioners,

v.

MENTOR CORPORATION;
LINDA RADOVAN WILLIAMSON,
as executrix of the Estate of CHEDOMIR RADOVAN;
HILTON BECKER, M.D.; and BEVERLEY ANNE BECKER;

Respondents.

**APPENDIX TO
PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**

JOHN J. CAVANAUGH
77 West Washington Street
Chicago, Illinois 60602
(312) 346-1200

*Counsel of Record for
Petitioners*

Of Counsel:

ARTHUR A. OLSON, JR.
DONALD A. PETERSON
RICHARD P. BEEM
NEUMAN, WILLIAMS,
ANDERSON & OLSON

77 West Washington Street
Chicago, Illinois 60602
(312) 346-1200

March 14, 1990

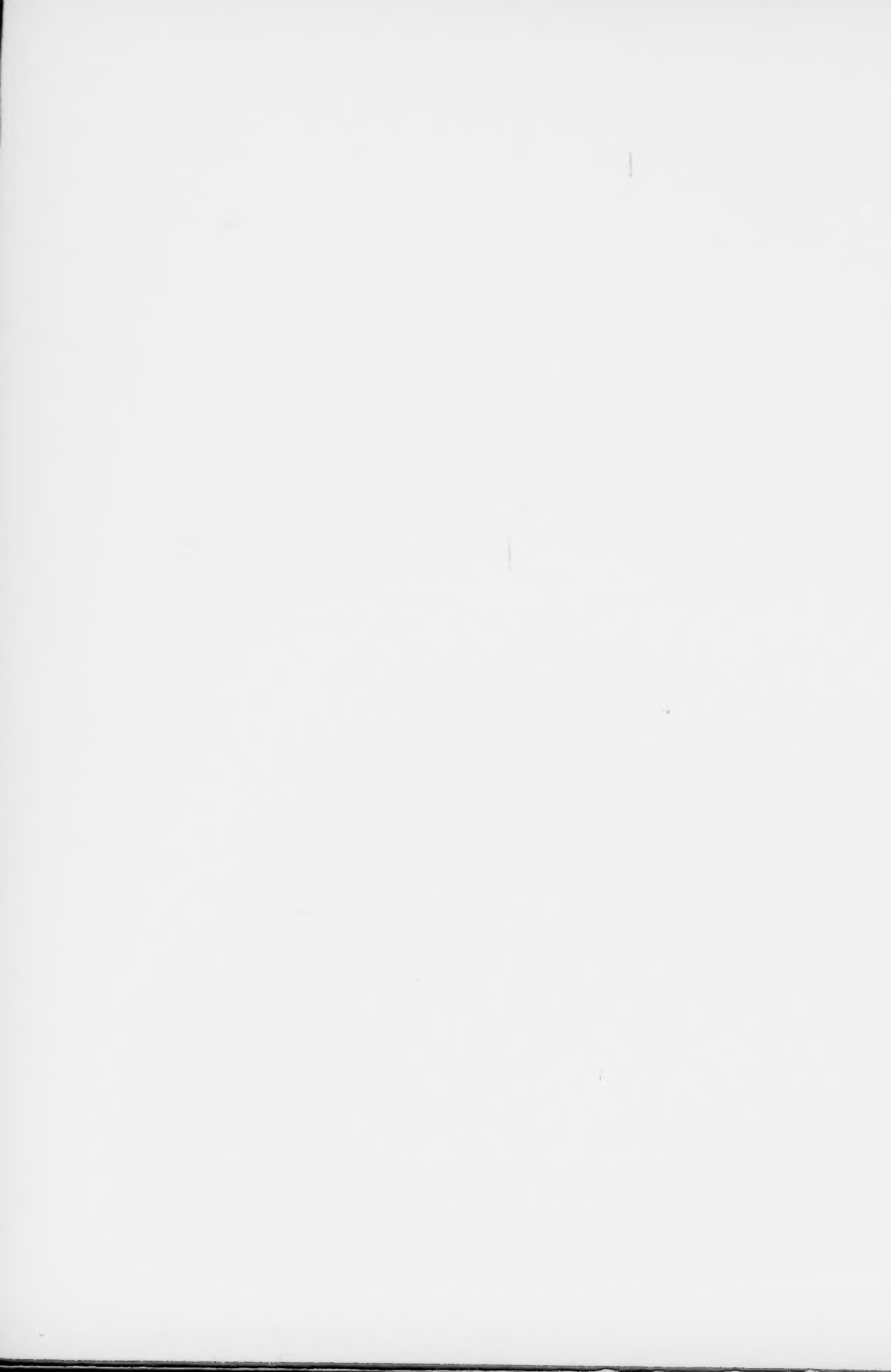


TABLE OF CONTENTS
APPENDIX TO PETITION FOR CERTIORARI
(Appendix Bound Separately)

	<u>Page</u>
Opinion of the United States Court of Appeals For The Federal Circuit Decided November 9, 1989	A-1
District Court Judgment on The Verdict Dated October 3, 1988.....	A-4,5
Order Of The United States District Court For the Central District Of California Granting Defen- dant's Motion For Judgment Notwithstanding The Verdict Dated January 27, 1989.....	A-6
District Court Findings of Fact And Conclusions of Law Dated February 27, 1989.....	A-12
District Court Judgment Granting The Judgment Notwithstanding The Verdict Dated February 27, 1989.....	A-48
District Court Order Denying Defendant's Motion To Amend Findings of Fact And Conclusions Of Law, And Granting Defendant's Motion For A New Trial Dated April 24, 1989.....	A-50
Federal Circuit Judgment Reversing The District Court Granting of Judgment Notwithstanding The Verdict Dated November 9, 1989	A-52
Federal Circuit Order Denying The Petition For Rehearing By The Panel Dated December 14, 1989.....	A-53,54
Federal Circuit Order Denying The Suggestion For Rehearing In Banc Dated January 8, 1990.....	A-56,57
Defendant's Motion For Judgment Notwithstand- ing The Verdict And Alternative Motion For New Trial Dated October 5, 1988.....	A-58
Defendant's Motion To Amend The Findings of Fact And Conclusions Of Law Dated March 17, 1989.....	A-68

TABLE OF CONTENTS TO APPENDIX (Cont'd)

	<u>Page</u>
28 U.S.C. § 2071—Rule-Making Power Generally .	A-98
28 U.S.C. § 2072—Rules of Procedure And Evidence; Power to Prescribe	A-99
Federal Rules Of Civil Procedure: Rule 50(b),(c)— Motion For A Directed Verdict And For Judgment Notwithstanding The Verdict	A-99
Federal Rules Of Civil Procedure: Rule 59(b)— New Trials; Amendment of Judgments	A-100

Note: This opinion has not been prepared for publication in a printed volume because it does not add significantly to the body of law and is not of widespread legal interest. It is a public record. It is not citable as precedent. The decision will appear in tables published periodically.

**United States Court of Appeals
for the Federal Circuit**

89-1302, -1348, -1472

MENTOR CORPORATION,
LINDA RADOVAN WILLIAMSON,
as executrix of the Estate of CHEDOMIR RADOVAN;
HILTON BECKER, M.D.; AND
BEVERLEY ANNE BECKER,

Plaintiffs-Appellants,

v.

COX-UPHOFF CORPORATION AND
COX-UPHOFF INTERNATIONAL,

Defendants/Cross-Appellants.

DECIDED: November 9, 1989

Before RICH, MAYER, and MICHEL, *Circuit Judges.*

PER CURIAM.

DECISION

The judgment notwithstanding the verdict in favor of Cox-Uphoff entered by the United States District Court for the Central District of California, No. CV 87-5611-JWC(Tx) (Jan. 30, 1989), is *reversed*, and the case is *remanded* with

instructions that the district court enter judgment on the jury verdict in its entirety and issue a permanent injunction pursuant to it. The findings of fact and conclusions of law supporting the judgment NOV, as well as the conditional order of a new trial, are *vacated*. Cox-Uphoff's cross-appeal from the district court's order denying its motion to amend findings of fact and conclusions of law is *dismissed*, and Cox-Uphoff will pay Mentor's attorney fees incurred in responding to the cross-appeal. Mentor will have its costs.

OPINION

"The district court focused on evidence in support of [Cox-Uphoff's] contentions, rather than on evidence in support of the jury's findings. That approach constitutes reversible legal error, particularly where, as here, it involves a virtual disregard of substantial evidence on which the jury could reasonably have reached a contrary determination." *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1572 (Fed. Cir. 1986). We agree with Mentor that substantial evidence exists in the record to support the jury's findings; that is all Mentor need show to convince us that the trial judge erred in granting Cox-Uphoff JNOV. *Id.* at 1571.

Not only did the district court disregard the findings of the jury and the supporting record evidence, but it also supplied a defense that Cox-Uphoff chose not to pursue and that accordingly was not tried: the invalidity of the Becker patent under section 102(b). The failure of Cox-Uphoff's counsel to acknowledge, indeed its reliance on, the district court's error is disingenuous.

As for the cross-appeal, this court twice before has addressed the timeliness of Cox-Uphoff's post-judgment motion. *See* Orders dated April 3, 1989, and May 23, 1989. In the April 3 order we clearly stated that the motion, filed March 17, 1989, was untimely because not filed within ten days of entry of the final judgment on February 28, 1989.

See Fed. R. Civ. Pro. 59. Therefore, we dismiss Cox-Uphoff's frivolous cross-appeal and award attorney fees in favor of Mentor.

The district court's conditional grant to Cox-Uphoff of a new trial in response to this untimely motion is of no effect. The ten day time period provided in Rule 59 is mandatory and jurisdictional and cannot be extended in the discretion of the district court. See *Fiester v. Turner*, 783 F.2d 1474, 1476 (9th Cir. 1986); *Scott v. Younger*, 739 F.2d 1464, 1467 (9th Cir. 1984).

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

MENTOR CORPORATION, *et al.*,

Plaintiff,

VS

COX-UPHOFF CORPORATION,
et al.,

Defendant.

ENTERED
OCT. 4, 1988

CV87-5611-JWC for ER

JUDGMENT ON THE
VERDICT
(For Plaintiff)

This cause having been tried by the Court and a Jury, before the Honorable JESSE W. CURTIS, Judge presiding, and the issues having been duly tried and the Jury having duly rendered it's verdict; now, therefore, pursuant to the verdict,

IT IS ORDERED, ADJUDGED AND DECREED that the plaintiff(s) MENTOR CORPORATION, *et al.*, have and recover of and from the defendant(s) COX-UPHOFF CORPORATION, *et al.*, the sum of \$486,000.00 as to the Becker Patent, together with costs, taxed in the sum of _____

Clerk, U.S. District Court

Dated: October 3, 1988

By SHIRLEY C. FRACT

Deputy Clerk

CV 49 (3/87) JUDGMENT ON THE VERDICT
(For Plaintiff)

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

MENTOR CORPORATION, *et al.*,

Plaintiff,

vs

COX-UPHOFF CORPORATION,
et al.,

Defendant.

ENTERED
OCT. 4, 1988

CV87-5611-JWC for ER

JUDGMENT ON THE
VERDICT

(For Plaintiff)

This cause having been tried by the Court and a Jury, before the Honorable JESSE W. CURTIS, Judge presiding, and the issues having been duly tried and the Jury having duly rendered it's verdict; now, therefore, pursuant to the verdict,

IT IS ORDERED, ADJUDGED AND DECREED that the plaintiff(s) MENTOR CORPORATION, *et al.*, have and recover of and from the defendant(s) COX-UPHOFF CORPORATION, *et al.*, the sum of \$204,000.00 as to the Radovan Patent, together with costs, taxed in the sum of _____

Clerk, U.S. District Court

Dated: October 3, 1988

By SHIRLEY C. FRACT

Deputy Clerk

CV 49 (3/87) JUDGMENT ON THE VERDICT
(For Plaintiff)

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

MENTOR CORPORATION, <i>et al.</i> ,	}	NO. CV 87-5611-JWC (Tx)
<i>Plaintiffs,</i>		
v.	}	MEMORANDUM AND ORDER GRANTING DEFENDANTS' MOTION FOR JUDGMENT N.O.V.
COX-UPHOFF CORPORATION,		
<i>et al.</i> ,		
<i>Defendants.</i>		

This court has before it defendants' motion for judgment n.o.v. in this patent case in which the jury rendered a verdict in favor of the plaintiffs, holding plaintiffs' patents valid and infringed by the defendants, and awarding substantial damages.

Plaintiffs' claims are based upon two patents. The earliest is the Radovan patent No. 4,217,889, filed August 19, 1980, entitled "Flap Development Device and Method of Progressively Increasing Skin Area." The second patent filed February 17, 1987, will be known as the Becker patent after its inventor Hilton Becker. This patent is No. 4,643,733 and is entitled "Permanent Reconstruction Implant and Method of Performing Human Tissue Expansion."

The basic tissue expander was discussed in an article in "Plastic and Reconstructive Surgery" for February 1959, which defines the tissue expander as a balloon that is flexible in all directions when expanded by a tube passing through the skin. This publication discloses the production of skin expansion by the gradual inflation of a subcutaneous balloon which was well known before the Radovan patent was issued and, therefore, constitutes prior art. The one problem encountered in the use of this balloon-type tissue expander was that it exerted localized pressure unevenly on the portion of

the body underlying the tissue expander. The Radovan patent No. 889 claims to overcome this problem by a nonextensible base along with a slack cover as illustrated in Figure 2 of the Radovan patent drawings.

The patent describes a tissue expander having a base that is *substantially nonextensible*, either inflexible or stiffly flexible, thereby causing its area shape to be retained. The stiffness of the base prevents excessive localized forces from being exerted beneath the base or against underlying muscle.

Plaintiffs accuse the defendants of infringing claims 23-27, 29 and 30-31 of the Radovan patent No. 889, which reads as follows:

Claim 23. A device to progressively increase skin area over a prolonged period of time after surgical implantation, comprising: a highly expandable skin stretching chamber joined in flow communication with a substantially less expandable puncture chamber; said skin stretching chamber having a shape retaining base that is substantially stiffer than a flexible cover of the skin stretching chamber for controlling the shape of such skin stretching chamber during progressive enlargement; and the skin stretching chamber is collapsible to a volume substantially less than one half of its inflatable volume for insertion under a section of skin, whereby the skin stretching chamber can be progressively enlarged by periodic hypodermic injections through the skin into the puncture chamber.

The other claims allege to have been infringed are all dependent claims; consequently, Claim 23 is controlling.

The defendants manufacture a versafil tissue expander line which consists of a balloon flexible in all directions when expanded by a tube passing through the skin, both the design and performance of which come within the teachings of prior art, except the plaintiffs' claim that the device has a shape

retaining base that is substantially stiffer than the flexible cover for controlling the shape of the skin stretching chamber. The defendants manufacture and sell versafil tissue expanders that have a "backing" and unbacked expanders, but only the back expanders are alleged to infringe Claim 23.

The precise issue, therefore, is does the versafil expander have a shape retaining base that is substantially stiffer than a flexible cover of the skin stretching chamber. Witness Paulson testified that the backed versafil tissue expanders consists of an injection port (a "less exposable puncture chamber"), an all silk silicone envelope (a "skin stretching chamber") on to which a piece of silicone sheeting is bonded. This sheeting has approximately the same hardness or durometer reading as the envelope. Neither the sheeting nor the envelope would be considered to be either rigid or stiff. The shape of either the inflated or uninflated versafil expanders are not determined by the sheeting bonded to one side of the envelope, but by the shape of the mandrel on which the envelope is cast. Hence, the versafil expanders do not have a "shape retaining base that is substantially stiffer than the flexible cover."

In clinical use a versafil expander is inflated with sheeting by "periodic hypodermic injections through the skin into the puncture chamber." Inflated expanders illustrated in Figures 4-13 in the Radavon patent all have perfectly flat bases, and inflated versafil expanders, on the other hand, have both the envelope and the sheeting extended. On the versafil expanders the sheeting bonded to one side of the envelope is there for the purpose of hiding cosmetic flaws in the envelope and to make the tissue expander a little easier to insert into the surgical pocket. It is also apparent to both those who use and to those who design tissue expanders that a tissue expander is still clinically functional without a nonextensible or shape retaining base.

A physical examination of the two devices demonstrates clearly the rigidity of the base of the Radavon device which

must be substantial in order to distribute the pressure evenly over the base in order to effect the result that Radavon claims. Whereas, the base of a versafil expander base is not substantially stiffer than the flexible cover of the stretching chamber and does not produce the result that the Radavon patent claims.

I hold, therefore, that although the Radavon patent is valid, given the presumption of validity and the insufficiency of the evidence in the record to overcome such presumption, the versafil device does not infringe Claims 23-27, 29-31 of the Radavon patent 889.

BECKER PATENT

The plaintiffs also complain that the defendants have infringed Claims 1, 2, 3, 4, 7 and 8 of the Becker patent. Defendants answer that the patent in its entirety is invalid as it does not present a patentable combination under 35 U.S.C. §103.

In December 1982, Dr. Becker presented a publication entitled "Breast Reconstruction Using an Inflatable Breast Implant With Detachable Reservoir," which article was revised in June 1983, shortly after his application for patent was filed. In this publication he evaluates his discovery as follows:

"... the standard Heyer-Schulte type inflatable breast implant has been modified to enable a reservoir to be attached and detached at a side filling valve. The breast implant, therefore, functions initially as a tissue expander and then remains in position as a permanent once the reservoir is removed."

Page 678 of Exh. 223.

In this publication Dr. Becker admits Claim 1 shows a combination of the "standard Heyer-Schulte type implant"

which is prior art with a means of injecting the saline solution into the implant by way of "a reservoir" of a type shown. This reservoir is shown in the Radavon Patent 889 and is therefore prior art.

As late as July 1987, Dr. Becker was still publishing how he came about producing his Permanent Tissue Expander. On page 519 of Exh. 206, he states as follows: "This concept was initially achieved by attaching an injection dome to the free end of the filling tube that is commonly used to inflate a saline-inflatable implant." This acknowledged substitution is not a patentable combination under 35 U.S.C. § 103.

It appears that the patent examiner was of this opinion when he initially rejected the Becker patent application claims based upon the combination of the Heyer-Schulte implants in combination with the Radavon 889 patent. During the process, however, he came up with other reasons for rejecting the patent application which was apparently amended to satisfy these later objections. However, the examiner's original opinion that the application did not present a patentable combination was lost in the shuffle and was not again considered.

In his publication heretofore referred to, Dr. Becker describes his advance in the art as follows:

Since first described the inflatable breast implant has undergone several changes. Initially, the filling tubes were fixed to the implant, the newer implants now have selfsealing valves with detachable filling tubes by attaching a reservoir to the filling tube a regular inflatable breast implant is converted into a tissue expander.

On page 678, he states: "Over a period of twenty months, twenty-five cases representing twenty-three patients with a total of thirty-four breasts have been operated on using this implant." Since the last revision of the article is stated to have been made June 27, 1983, less than four months after

the Becker application filing date, by his admission, the alleged invention was in use more than one year prior to the application of the filing date and therefore is barred under 35 U.S.C. § 103.

I therefore hold that the Becker patent is invalid as it consists of an unpatentable combination of prior art concepts, and that the patented device was in use for more than one year prior to the application for patent.

Judgment shall therefore be for the defendants and against the plaintiffs, defendants to prepare and file proposed findings of fact and conclusions of law.

DATED: January 27, 1989

JESSE W. CURTIS

JESSE W. CURTIS

United States District Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA

MENTOR CORPORATION, <i>et al.</i> ,	}	No. CV 87-5611-JWC (Tx) FINDINGS OF FACT AND CONCLUSIONS OF LAW
<i>Plaintiffs.</i>		
v.		
COX-UPHOFF CORPORATION.		
<i>Defendant.</i>	}	

This cause having been tried by the Court and a Jury, before the Honorable Jesse W. Curtis, Judge Presiding, during the period September 13 through 22, 1988. The Jury rendered a verdict in favor of the plaintiffs, holding plaintiffs' patents valid and infringed by the defendant, Cox-Uphoff Corporation,* and awarding substantial damages and Judgments were entered on the verdicts.

Defendant moved for Judgment N.O.V. pursuant to F. R. Civ. P. 50(b) to have the Judgments set aside in accordance with the defendant's motion for a directed verdict. The Court having heard the testimony and having examined the proofs offered by the respective parties did, on January 30, 1989, grant defendant's motion for Judgment N.O.V. and ordered that Judgment be entered for the defendant and against the plaintiffs.

* Plaintiffs obtained a default judgment against Cox-Uphoff International, one of the originally named defendants. However, there is no evidence that Cox-Uphoff International continues to exist or that if it does it has any rights or obligations pertaining to the subject matter of this case. Consequently, these findings of fact and judgment are intended to relate to the defendant Cox-Uphoff Corporation only.

Accordingly, the Court makes its Findings of Fact and Conclusions of Law as follows:

FINDINGS OF FACT

It is true that:

I. General Background

Introduction

1. Plaintiff, Mentor Corporation (Mentor), is a Minnesota corporation, having its principal place of business in Goleta, California.

2. Plaintiff, Linda Radovan Williamson is the executrix of the Estate of Chedomir Radovan and is an individual with her domicile and residence in the State of Illinois.

3. Plaintiff, Hilton Becker, M.D., is a resident of Palm Beach, Florida.

4. Plaintiff, Beverly Anne Becker, is the wife of the plaintiff, Dr. Hilton Becker, and is a resident of Palm Beach, Florida.

5. Cox-Uphoff Corporation (Cox-Uphoff), is a California corporation, having its principal place of business in Carpenteria, California.

6. Cox-Uphoff International, is a Nevada corporation, having an address in Carpenteria, California.

7. This action was originally brought by the plaintiff, Mentor Corporation (Mentor), against the defendant Cox-Uphoff International, for infringement of U.S. patents 4,217,889 ('889) and 4,643,733 ('733) on August 25, 1987. The Complaint was first amended to add the Cox-Uphoff Corporation, a California corporation, as a party defendant. Cox-Uphoff International is not conducting any business of any kind. Cox-Uphoff Corporation defended the lawsuit.

8. U.S. patent 4,217,889 was granted on August 19, 1980, in the names of Chedomir Radovan and Rudolf R. Schulte as joint patentees. The '889 patent was based on an application bearing Serial No. 723,338 that was originally filed in the U.S. Patent and Trademark Office on September 15, 1976. The original application was abandoned, in favor of a continuation application bearing Serial No. 926,484 on July 20, 1978.

9. U.S. patent 4,643,733 was granted on February 17, 1987, in the name of Hilton Becker as the sole patentee. The '733 patent was based on a patent application bearing Serial No. 481,912 filed in the U.S. Patent and Trademark Office on April 4, 1983.

10. The joint patentee Chedomir Radovan is deceased. The second amendment to the Complaint added the executrix of the Estate of the joint patentee Radovan as a party plaintiff, representative of the ownership interest of the deceased patentee of the '889 patent. The plaintiff-executrix is Linda Radovan Williamson. The ownership interest of the other joint patentee, Schulte, is owned by the plaintiff, Mentor, as a result of succeeding to an assignment of Schulte's entire right, title and interest executed by Schulte to the Heyer-Schulte Corporation.

11. The Becker '733 patent is the subject of an exclusive license from Becker to Mentor. The title to the '733 patent is in the names of Dr. and Mrs. Hilton Becker as tenants in the entirety. Dr. and Mrs. Becker have been added to the Complaint as party plaintiffs upon agreement of Mentor and Cox-Uphoff, and they were added as party plaintiffs by the Court's Pre-Trial Conference Order.

12. Dr. Chedomir Radovan exclusively licensed his rights under his patent application Serial No. 723,338 on December 14, 1976, to Heyer-Schulte Corporation. Mentor has succeeded to Heyer-Schulte's patent rights under the Radovan license agreement.

13. While the Becker patent application, Serial No. 481,912, was pending in the U.S. Patent and Trademark Office, Dr. Becker entered into an exclusive license agreement for the manufacture, use and sale of the subject matter of the Becker patent application and any patent granted thereon on June 3, 1985 (Ex. 274).

14. All the parties with an ownership interest in U.S. patents 4,643,733 and/or 4,217,889, the two patents in suit, have been joined as parties plaintiff. The party plaintiffs are collectively referred to herein as "Mentor."

15. The Schulte-Radovan patent 4,217,889 was granted with 31 claims for a flap development device and method of progressively increasing skin area. Of the 31 claims, Mentor accused the defendants of infringing claims 23-27, 29, and 30-31 by the manufacture, use and sale of the "Versafil" backed tissue expanders. The defendants' unbacked tissue expanders were not alleged to infringe the claims of the '889 patent.

16. The Becker patent 4,643,733 was granted on February 17, 1987, with 8 claims for a permanent reconstruction implant and method of performing human tissue expansion. Mentor has complained that the defendants have infringed claims 1, 2, 3, 4, 7 and 8 of the eight claims of the Becker patent by the manufacture, use and sale of their RDL-Xpand reverse double lumen mammary prosthesis.

RADOVAN-SCHULTE PATENT 4,217,889

17. The Radovan-Schulte patent claims cover an expansion device for implementation beneath the skin and subcutaneous layer to cause the surface area of the skin which overlays the device to be stretched for providing a flap to be used in reconstructive surgery. The device comprises an envelope with a substantially non-extendable base and a cover. The cover is flexible and when the device is in an unexpanded condition, the cover is slack. The device is

highly expandable in response to fluid conveyed between the cover and the non-extensible base. The base causes the device to expand away from the non-extensible base or unidirectionally. (The base does not respond to the fluid by expanding.) The device is expanded by the provision of a reservoir coupled to a conduit and the inside of the thus defined envelope. Fluid such as a saline solution is injected into the envelope by a hypodermic needle piercing the reservoir and injecting the fluid therein and into the fill tube, thereby into the envelope. When the device is implanted below the skin, the needle pierces the reservoir through the overlying skin. The conduit or fill tube of the expansion device may be coupled to the envelope by means of a connector coupled to the envelope and the reservoir-fill tube combination to permit the reservoir and fill tube to be disconnected as a unit from the expansion device at the connector. The device includes a normally closed check valve to permit fluid to be introduced into the envelope and maintained therein.

18. The Radovan-Schulte tissue expander as disclosed in the '889 patent is restricted to a unidirectional, highly expansible device due to its substantial non-extensible base, as illustrated by the progressive expansion of the device in Figures 4-7 of the '889 patent drawings wherein the device is illustrated below the tissue to be expanded.

The History of Radovan-Schulte Patent Applications

19. The record reveals the applicants admitted before the Patent and Trademark Office upon the filing of their patent application the prior development of a tissue expander in the form of a balloon that was flexible in all directions, as noted in column 1, lines 43-56, of the '889 patent with reference to the February, 1957, publication of Dr. Neumann in "Plastic and Reconstructive Surgery."

20. The 1957 publication of Dr. Neumann disclosed to the art a basic tissue expander in the form of a balloon that is flexible in all directions when expanded by a tube passing

through the skin. The Neumann publication discloses the production of skin expansion by the gradual inflation of a subcutaneous balloon which was well-known before the Radovan et al patent application was filed in the Patent and Trademark Office and therefore constitutes prior art. One problem encountered in the use of this balloon type tissue expander was that it exerted localized pressure unevenly on the portion of the body underlying the tissue expander as the Radovan et al '889 patent discusses in column 1, lines 50-55.

21. The Radovan et al '889 patent claims to improve over the Neumann balloon-type tissue expander for overcoming the problem of exerting localized forces unevenly on the portion of the body underlying the tissue expander by providing a tissue expander having a non-extensible base along with a slack cover as illustrated in Figure 2 of the Radovan patent drawings.

22. The '889 patent describes a tissue expander having a base that is substantially non-extensible, either inflexible or stiffly flexible, thereby causing its area shape to be retained. The stiffness of the Radovan base prevents localized forces from being exerted beneath the base or against underlying muscle.

23. The highly expandable chamber results from the patented embodiment by having "slack" in the cover to avoid stretching the material. This is produced by the cover having random wrinkles and to expand unidirectionally, as illustrated in Figures 2-7 of the '889 patent. The fully distended condition of the patented tissue expander is illustrated in Figure 7 of the patent drawings.

24. The arguments of Radovan's patent counsel before the Patent and Trademark Office, in distinguishing over the prior art, stated that the claimed device has a substantially non-extensible base and a flexible cover with a variable external size. In addition, the base was characterized as

including a "substantially stiffer shape retaining base..." These arguments resulted in the granting of the claims in the '889 patent.

II. Validity of the 4,217,889 Patent

A. Scope and Content of Prior Art

25. The references before the Patent and Trademark Office were as follows:

(a) The structure of the Neumann balloon-type tissue expander was described in the February, 1957, publication of "Plastic and Reconstructive Surgery," Vol. 19, No. 1, pp. 124-130 in an article entitled "The Expansion of an Area of Skin by Progressive Distention of a Subcutaneous Balloon" as described hereinabove and the problems experienced with the balloon-type tissue expander.

(b) The patent examiner cited the following U.S. patents showing various aspects of the Radovan et al claimed structures:

3,538,917	11/1970	Selker
3,665,520	5/1972	Perras et al
3,744,063	7/1973	McWhorter et al
3,831,583	8/1974	Edmunds, Jr. et al
3,852,833	12/1974	Koneke et al
3,863,622	2/1975	Buuck
3,934,274	1/1976	Hartley, Jr.

None of the aforementioned patents discloses the claimed tissue expander of the Radovan patent, namely, an expander having a substantially non-extensible base for causing its area shape to be retained.

26. The following additional references, not before the Patent Office, were relied on by the defendant at the trial to further show the state of the art:

(a) Sanders, et al—U.S. Patent 3,919,724

The patent discloses an injection port that works like the port or reservoir in the Radovan-Schulte patent. The patent includes a radio-opaque valve to increase or decrease the amount of fluid within the flexible container from a fluid source. The Sanders' container is totally collapsible during insertion. Embodiments are also disclosed with a similar valve for remote inflation.

(b) Boone—U.S. Patent 3,600,718

This patent discloses an injection port that allows an implanted shell to be inflated with saline. A sealing gel is used through which the inflation stem 12 passes. The shell is provided with reinforcing material 13 fixed to the back of the shell.

(c) McGhan—U.S. Patent 3,852,832

This patent discloses a prosthesis which is fillable with a gel or saline through a "Bronx cheer" type of filler valve. The patent also discloses a prosthesis with a relatively less flexible back area relative to the front.

(d) Perras—U.S. Patent 3,681,787

This patent discloses a breast prosthesis that permits the injection of a gel after it is implanted. The breast prosthesis includes a base surrounded with a solid non-extensible rubber rim 22.

(e) Koken—Japanese Patent 2320/72 and Registration 956,809

This patent discloses an implantable device that can be inflated after it is installed within the body. The disclosed prosthesis includes a soft elastic membrane and a flat back with a brim extending in a direction outwardly of the back.

(f) Legun—French Patent 2,199,266

This patent discloses a sac that can be inflated with isotonic saline solution after being implanted by use of a hypodermic needle through the tissue.

(g) Lynch—U.S. Patent 3,883,902

This patent discloses an implantable prosthesis having two lumens that permits the addition of material after implantation.

(h) Arion—U.S. Patent 3,860,969 and Mohl et al—U.S. Patent 3,663,968

Both of these U.S. patents disclose implantable prostheses with a chamber constructed of two separate materials for the front and back walls.

(i) Schulte—U.S. Patent 3,310,051

This patentee, Schulte, is the same Rudolph Schulte who is a joint patentee in the Radovan-Schulte tissue expander patent in issue in the litigation.

This Schulte patent discloses a surgically implantable reservoir having a front wall and a rear wall of different thicknesses. It appears that due to the relative differences in thicknesses between the two walls, the second wall would be inherently more flexible than the rear wall.

(j) Heimlich—U.S. Patent 3,605,749 and Schiff—U.S. Patent 3,656,873

Each of these U.S. patents discloses surgical devices incorporating a check valve similar to that disclosed in the Radovan-Schulte patent. In the Heimlich patent, the element 17 is the valve. In the Schiff patent, the valve is illustrated in Figure 3 as elements 34 and 36.

These patents establish the use of stiff-backed bases for prostheses of various configurations.

B. Prior Art, Contrasted to the Claims of the 4,217,889 Patent

27. The Hartley, Jr., patent 3,934,274 and the Perras et al patent 3,665,529 were relied on by the patent examiner as examples of implantable prostheses and were distinguished over by counsel that neither taught expansion of the prosthesis after implantation without surgical re-entry.

28. The Sanders et al patent 3,919,724 disclosed a device that was totally collapsible, except for the valve, during insertion, but was not considered by the patent examiner.

29. The Perras et al U.S. patent 3,681,787 disclosed a breast prosthesis with a solid non-extensible rubber rim but was not considered by the patent examiner.

30. None of the prior art patent references taught or specifically suggested the use of a tissue expander, as contrasted to prior art prostheses of Finding No. 26, having a base that is substantially non-extensible, either inflexible or stiffly flexible, thereby causing its area shape to be retained. The stiffness of the Radovan expander base prevents excessive localized forces from being exerted beneath the base or against underlying muscle in a tissue expander. Radovan and Schulte addressed this problem of the prior art balloon-type tissue expanders.

C. Mentor-Dow License (Exhibit 309)

31. Mentor asserted the '889 patent against the Dow Corning Corporation (Dow) of Midland, Michigan. Dow advised Mentor of their claim of file wrapper estoppel in the Radovan et al file history, Exhibit 285. This is the same position as the defendants found to be true.

32. Mentor granted Dow a non-exclusive license under the '889 patent to make, use and sell tissue expanders of a special type. Mentor and Dow agreed royalties were due Mentor provided the Dow tissue expanders have a base which is reinforced such that the base does not stretch throughout its area.

D. The Level of Ordinary Skill in the Art

33. Based on the prior art patent teachings and knowledge of tissue expanders of various designs, the level of skill required to design a tissue expander would require the application of the level of skill associated with a medical doctor practicing tissue expansion and breast reconstruction. The doctor should have a familiarity with human physiology and the mechanical properties and biocompatibility of synthetic polymers.

E. The Non-Obviousness of the 4,217,889 Patent

34. The Court is of the opinion that none of the prior art, either cited by the Patent Office or the additional art cited by the defendant, would lead one skilled in the art to use a tissue expander having a substantially non-extensible base as claimed immediately prior to the filing of the original Radovan et al patent application on September 15, 1976.

III. Infringement

A. The Accused "Versafil" Expander

35. Cox-Uphoff manufactures, uses and sells tissue expanders that are sold as the "Versafil" tissue expanders. The "Versafil" tissue expanders are produced with "backing" and unbacked expanders. Only the backed expanders were accused to infringe.

36. The defendants' backed "Versafil" tissue expanders are constructed of two layers forming a flat envelope with the base and cover overlying one another in a flat condition when empty ("zero volume") and have an opening in the base. The opening includes a normally closed valve that opens in response to the insertion of a fill tube therein. The opposite end of the fill tube is adapted to receive a fluid such as air or a saline solution to rapidly introduce the fluid into the

envelope to expand it. The fill tube is removable and when removed, it allows the valve to close again. The envelope can be continuously expanded by means of a reservoir-fill tube combination connected to the envelope. Hypodermic injections introduce fluid into the reservoir for periodic expansion of the envelope.

37. The defendants' "Versafil" tissue expander comprises a balloon flexible in all directions when expanded by a tube passing through the skin, both the design and performance of which come within the teachings of the prior art.

38. The defendants established that the "backed" "Versafil" tissue expanders include an injection port (a "less expandable puncture chamber"), and an all silicone envelope (a "skin stretching chamber") onto which a piece of silicone sheeting is bonded. This silicone sheeting has approximately the same hardness or durometer reading as the envelope. Neither the sheeting nor the envelope would be considered to be either rigid or stiff. The shape of either the inflated or uninflated "Versafil" tissue expanders are not determined by the sheeting bonded to one side of the envelope, but by the shape of the mandrel on which the envelope is cast.

39. The defendants further established that in clinical use, a "Versafil" tissue expander is inflated with saline by "periodic hypodermic injections through the skin into the puncture chamber."

40. The inflated tissue expanders illustrated in Figures 4-13 in the Radovan et al '889 patent all have perfectly flat bases.

41. The inflated "Versafil" tissue expanders of the defendants have both the envelope and the sheeting extended.

42. The defendants also established that on the "Versafil" tissue expanders, the sheeting bonded to one side of the envelope is there for the purpose of hiding cosmetic flaws in the envelope and to make the tissue expander a little easier to insert into the surgical pocket.

43. It is apparent to both those who use and to those who design tissue expanders that a tissue expander is still clinically functional without a non-extensible or shape-retaining base.

44. The Radovan-Schulte patent in suit, No. 4,217,889, is directed to a flap development device or tissue expander as defined by apparatus claims that have been accused as being infringed, namely, claims 23-27 and 29. Apparatus claim 23 of said patent reads as follows:

Claim 23. A device to progressively increase skin area over a prolonged period of time after surgical implantation, comprising:

- (a) a highly expandable skin stretching chamber joined in flow communication with a substantially less expandable puncture chamber;

- (b) said skin stretching chamber having a shape retaining base that is substantially stiffer than a flexible cover of the skin stretching chamber for controlling the shape of such skin stretching chamber during progressive enlargement; and

- (c) the skin stretching chamber is collapsible to a volume substantially less than one half of its inflatable volume for insertion under a section of skin, whereby the skin stretching chamber can be progressively enlarged by periodic hypodermic injections through the skin into the puncture chamber.

Apparatus claims 24 through 27 and 29 are all dependent claims and dependent on claim 23. Claim 23 is controlling.

45. The Radovan-Schulte patent in suit No. 4,217,889 is also directed to a method of progressively increasing skin area. The method claims that have been accused as being

infringed are claims 30 and 31. Method claim 30 of said patent reads as follows:

Claim 30. A method of progressively increasing skin area over a prolonged period of time, comprising the steps of:

(a) placing beneath the skin a device that includes a highly expandable skin stretching chamber joined in flow communication to a substantially less expandable puncture chamber, said skin stretching chamber having a base that is substantially stiffer than a flexible cover of the skin stretching chamber, and such skin stretching chamber is collapsible to a volume substantially less than one half of its inflatable volume for insertion under a section of skin; and

(b) progressively enlarging the skin stretching chamber by periodic hypodermic injections through the skin into the puncture chamber.

Method claim 31 is a dependent claim that is dependent on claim 30 and therefore method claim 30 is controlling. Both method claims 30 and 31 include the structural feature of the tissue expander defined in claim 23, namely, a tissue expander ("a device") "having a base that is substantially stiffer than a flexible cover of the skin stretching chamber".

B. Infringement

46. A physical examination of the Mentor tissue expanders demonstrates, clearly, the rigidity of the base element thereof must be substantial in order to distribute the fluid pressure within the chamber evenly over the base in order to effect the result of the Radovan et al patent claims.

47. A physical examination of the base of the accused "Versafil" tissue expander demonstrates that the base is not substantially stiffer than the flexible cover of the stretching

chamber and therefore does not have a "shape retaining base" to effect the result of Radovan patent claim 23, element (b), as recited in Finding 23.

C. Vexatious or Unjustified Infringement Claim

48. Prior to the initiation of the litigation and during the pre-trial proceedings in the litigation, Mentor did not specifically apply the Radovan et al patent claims to the Cox-Uphoff accused tissue expanders. Typical of Mentor's discovery responses are the Mentor Answers to Interrogatories 1, 2 and 4 as late as March 11, 1988, Exhibit 271, concerning the infringement claim. The response to Interrogatory No. 1 was supplemented by Exhibit 276, but not the response to Interrogatory No. 2. It is incredible that a patent owner could assert infringement of patent claims without revealing the application of the patent claims to a defendant's accused structures, long after commencing the litigation.

49. Mentor's Memorandum of Contentions of Fact and Law submitted in June, 1988, discussed the issue of infringement of the Radovan patent claims and the willful infringement of Cox-Uphoff's "stiff-backed" tissue expander as being "literally" covered by the accused patent claims in broad, general terms. A "detailed description" indicating the alleged representation of the manner the patent claims were infringed was attached to Mentor's Memorandum as Exhibit "C". The critical aspects of the patent claims were supported by conclusionary statements, such as the following statement as to patent claims 23:

"The CUI chamber has a shape retaining base that is reinforced with fabric mesh and is substantially stiffer than the flexible cover of the stretching chamber. . . . The base controls the shape of the stretching chamber during enlargement."

50. Mentor's expert patent witness testified on infringement, without reference to the prior art and the validity of

the patent claims, other than the presumption of patent validity, and applied them literally without any limitations as to the proper legal interpretation of the patent claims in the broad fashion represented in Finding No. 48. At no time was any proof submitted that the Cox-Uphoff tissue expanders were (1) flexible in all directions when expanded, (2) nor that the sheeting in the base of the "backed" Versafil expanders is rigid or stiff, (3) the base of the "Versafil" expander is substantially stiffer than the flexible cover of the stretching chamber to provide a "shape retaining base" as the Radovan patent claims.

BECKER PATENT 4,643,733

51. The Becker '733 patent discloses a single lumen mammary implant that is claimed to function in the capacity of a tissue expander capable of multi-directional expansion and capable of being expanded by percutaneous fluid injections or delayed filling into a reservoir or port connected by an attachable-detachable fill tube with the implant. When the implant is within the body, it may be periodically inflated by means of hypodermic injections through the body and into the reservoir for expanding the implant without the need for additional surgical re-entry. The completely expanded implant may have the reservoir and fill tube detached from the implant upon opening the body, and the detached implant maintained in the body permanently. The implant per se, including the valving, therefore, is based on the permanent breast prosthesis of Heyer-Schulte, the admitted prior art, as noted in the original Becker patent application as filed in the Patent and Trademark Office and now in the patent in column 2, lines 50-61, of the '733 patent. The Radovan '889, discussed hereinabove, was admitted to be prior art by Dr. Becker in his patent application as originally filed and now in his patent in column 2, lines 22-29.

The History of the Becker 4,643,733 Patent Application

52. The Becker patent application as filed in the Patent and Trademark Office on April 4, 1983, was marked up by

the applicant Becker, beginning with the title and through the Declaration executed by Hilton Becker on March 22, 1983. The marked-up application deleted certain matters and substituted other language therefor and added certain matters. The Declaration (that was previously executed) was similarly marked up. All the markings were initialed by the applicant and dated 3/23/83 in the margins of the application papers as filed in the Patent Office; see Exhibit 140.

An unmarked, unexecuted copy of the Becker patent application, Exhibit 219, reveals the language deleted from the application as filed in the PTO. A significant change reveals that the term "a delayed filling" was substituted for the blocked out words "subcutaneous expander" throughout the specification, patent claims, Declaration, and verified statement (declaration) claiming small entity status 37 CFR 1.9(f) and 1.27(b)—independent inventor.

53. The Declaration executed by the applicant Becker was in the usual form and included the acknowledgment of the duty to disclose information of which the applicant was aware and material to the examination of the patent application. The applicant Becker testified at the trial that he discussed this "duty to disclose" with his then patent attorney (deceased prior to issuance of the patent in suit) and he understood his "duty to disclose."

54. Prior to any examination of the Becker patent application by the Patent Office, the applicant's counsel attempted to comply with the "duty to disclose" by filing a "Statement Under 37 C.F.R. §1.56" identifying certain information that may be material to the examination of the patent application. The statement included a listing of the prior art and copies of each of the identified items. This information includes the prior work of Radovan disclosed in the patent specification, namely, the Radovan et al '889 patent and Dr. Radovan's prior publication and the Heyer-Schulte prior devices. See column 1, lines 22-62, of the '733 patent.

55. The '733 patent specification includes the material of the original application directed to the problem of the prior art implants, namely, the requirement for "two major surgical procedures." The first procedure required the insertion and use of a tissue expander for expanding the breast tissue and then removing the expander and substituting a permanent implant in the position of the expanded tissue; column 1, line 63, to column 2, line 8, of the '733 patent.

56. The '733 patent claims to eliminate the need for two surgical steps by requiring only a single major surgical procedure. This was accomplished by the provision of "a singular device which functions both as an expander and as a permanent implant." The implant is gradually expanded by percutaneous injections into the implanted reservoir for tissue expansion purposes. Upon completion of the expansion procedure, the reservoir and filling tube can be detached from the implant and removed from the body through a single small incision; column 2, lines 11-23, of '733 patent.

57. All of the original patent application claims were identically descriptive of the tissue expander of the admitted prior art, namely, the Radovan '889 patent, and Radovan publications as recited in Finding No. 55.

58. Patent examiner Ronald L. Frinks, a primary examiner, examined the Becker application and the prior art, including the prior art cited by the applicant and made all of the prior art of record in the Becker patent application. All of the original, principal Becker patent application claims were rejected by Examiner Frinks as unpatentable under 35 USC 103 over the teachings in either the citation of the Dow Corning publication or the Heyer-Schulte "Inflatable Mammary Prosthesis" publication in view of the teachings of the Radovan et al '889 patent. The examiner indicated it was an obvious expedient of choice to provide an attached reservoir on the detachable fill tubes to facilitate percutaneous injection fillings after implantation as the '889 Radovan et al patent taught such a feature to be old in the art.

59. In responding to the Office's rejection of the Becker claims, Becker's counsel did not amend any of the claims but argued for patentability. In counsel's arguments he, again, acknowledged that the Radovan expander was a "temporary expander" of the prior art and the "permanent implants" utilized a relatively rigid filling tube that excluded them from long-term attachment to a filling reservoir (4 to 8 week period during expansion).

60. Prior to further action by the patent examiner, a Supplementary Response to the rejection was filed by Becker. This supplemental response included the affidavit of H. Hollis Caffee, M.D., and his evaluation of the prior art. Dr. Caffee's knowledge was that no singular device was used to perform skin expansion and then left in place as a permanent implant prior to the disclosure in Becker's patent application. Dr. Caffee was of the opinion it would not be obvious to one skilled in the art to add a detachable reservoir to either the cited Heyer-Schulte or Dow Corning implants.

61. On re-examination, Examiner Frinks rejected the principal claims 1-5 as being "structurally anticipated" by the Radovan et al '889 patent under 35 USC 102. The examiner established the identity of the claimed subject matter and the teachings of the '889 patent.

Method claim 9 was allowed by the examiner, and indicated dependent claims 6-8 contained allowable subject matter.

62. Becker's patent counsel personally interviewed Examiner Frinks and discussed an amended version of original claim 1 and presented an amendment. The amendment of claim 1 was claimed to distinguish over the cited art by amending the characterization of the prosthesis as being "constructed substantially entirely of a relatively soft and flexible material." The claims were then allowed by the examiner and appear in their amended form in the '733 patent.

I. Validity of the Becker 4,643,733 Patent

The Scope and Content of the Prior Art

63. The references before the Patent Office were as follows:

(a) Radovan et al—Patent No. 4,217,889

Issued August 19, 1980 on "Flap Development Device and Method of Progressively Increasing Skin Area"

Claim 4 and lines 4-45 describe a tissue expander device which has a normally closed check valve and remote reservoir for fluid addition and removal. That reservoir is connected to the prosthesis in such a way that it is disconnectable through a small incision with the prosthesis remaining implanted.

(b) Boone—Patent No. 3,600,718

Issued August 24, 1971 on "Inflatable Prosthesis"

This patent discloses an inflatable mammary prosthesis with a removable filling stem. At the point of introduction of the filling stem through a hole in the shell, there is a capsule of sealing gel through which the stem passes. After implantation, the stem can be withdrawn and the capsule seals the mammary. Boone also considers the possibility of leaving the filling stem in the patient for addition or withdrawal of fluid at a later time and then the stem withdrawn. Boone does not say how the implanted fill stem is accessed at a later time; but with the advent of tissue expander reservoir filling ports in later years, it would appear obvious to one skilled in the art to use such a reservoir with Boone's invention.

(c) Lynch—Patent No. 3,883,902

Issued May 20, 1975 on "Variable Volume Prosthetic Assembly"

This patent describes a breast prosthesis that is capable of being filled via a removable connecting tube attached to a reservoir of fluid. A valve is provided within the tube for closing the tube after the fluid is dispensed.

(d) Lake—Patent No. 4,095,295

Issued June 30, 1978 on "Adjustable, Fluid Filled Breast Implant"

This patent describes a breast prosthesis without valves but with a filling tube for remote filling of the prosthesis after implantation. The remote valve can be accessed without major surgery for altering the volume of the prosthesis. Lake also mentions that fill tubes can be removed altogether from similar prostheses (lines 1-55).

(e) Austad—Patent No. 4,157,085

Issued June 5, 1979 on "Surgically Implantable Tissue Expanding Device and the Method of Its Use"

This patent describes a tissue expanding device that is formed of a permeable membrane inside which is material that establishes an osmotic potential for filling of the prosthesis with extracellular fluid. This device is also known as a self-inflating tissue expander. Though usually a temporary implanted device, Austad suggests that sometimes the device is not removed after the tissue has been expanded (permanent implant) (lines 2-20).

(f) Edmunds, Jr. et al—Patent No. 3,831,583

Issued August 27, 1974 on "Implantable Bulb for Inflation of Surgical Implements"

This patent describes an implantable bulb attached to an inflatable sac. The bulb is a reservoir which is designed to self-seal after needle puncture so that fluid

can be injected into the inflatable sac connected by a filling tube to the bulb. The system is totally implantable for long term or permanent use and yet is later controllable without surgery.

(g) Koneke et al—Patent No. 3,852,833

Issued December 10, 1974 on "Breast Prosthesis"

This patent describes a breast prosthesis which is inflatable via a removable filling tube. There is contained within the prosthesis a sealing device which seals the prosthesis from leakage after removal of the tube.

(h) Buuck—Patent No. 3,863,622

Issued February 4, 1975 on "Incontinence System and Methods of Implanting and Using Same"

This patent describes an inflatable cuff for the urethra. It includes a remote reservoir(s) connected by filling tubes to the cuff which allow post implantation inflation and deflation of the cuff. The system utilizes a number of valves to control flow and prevent unwanted leakage from the cuff.

(i) "Silastic Varifil Mammary Implant"

Dow Corning Brochure dated October, 1977

This brochure describes an inflatable breast prosthesis which contains an inlet opening with a normally closed valve and a detachable fill tube which can be removed after implantation.

(j) "Inflatable Mammary Prosthesis"

Heyer-Schulte Brochure No. 102031-002-02-280

This brochure describes an inflatable mammary prosthesis which contains an inlet opening and a normally closed valve and a detachable filling tube.

64. The following additional references not before the Patent Office were relied on by the defendants at the trial to further show the state of the art:

(a) Berson—Patent No. 4,246,893

Issued January 27, 1981 on "Inflatable Gastric Device for Treating Obesity"

This patent describes a device that is used to distend the stomach in order to reduce food intake. The device consists of a balloon with an attached filling tube and a reservoir for adjusting the volume of the balloon on a permanent basis.

(b) U—Patent No. 4,341,218

Issued July 27, 1982 on "Detachable Balloon Catheter"

This patent describes an inflatable, implantable balloon with a detachable filling catheter and a valve in the balloon to prevent leakage. The device is designed with a needle puncturable site (reservoir) at the end of the filling tube. The Becker device appears to contain all the elements of the U device, namely, (1) an inflatable balloon adapted for implantation with an inlet opening, (2) a normally closed valve in the opening, (3) a filling tube having one end detachably connected, and (4) a reservoir connected to the other end of the filling tube to controllably expand the device after implantation.

(c) Schulte—Patent No. 3,310,051

Issued March 21, 1967 on "Surgical Reservoir for Implantation"

This patent describes a device for surgical implantation which can be used as a reservoir for tubular connection with a selected region or area. The reservoir is used to add and withdraw fluid percutaneously from the selected area.

(d) Cox, Jr.—Patent No. 4,178,643

Issued December 18, 1979 on "Valve for Inflatable Prosthesis"

This patent describes a valve which can be used for sealing an inflatable prosthesis after detachment of a filling tube from the conduit of the valve. Claim 6 of the patent describes an inflatable prosthesis with an aperture and a valve attached to it. A fill tube may be detachably connected to the prosthesis for fluid adjustment.

(e) Bernhardt—Patent No. 2,698,436

Issued January 4, 1955 on "Bust Form"

This patent describes a breast prosthesis which is designed with a valve means through which the volume of the prosthesis may be replenished through the life of the device.

(f) Fountain—Patent No. 3,492,996

Issued February 3, 1970 on "Ventriculo-Atrial Shunt"

This patent describes a device for implantation into the brain for treating hydrocephalics. The device consists of a conduit for fluid addition, a conduit for fluid outlet, an inter-connecting system including a pump, and a one-way valve.

(g) Cohen—Patent No. 4,433,440

Issued February 28, 1984 on "Prosthesis Formed by Inner and Outer Inflatable Containers"

This patent describes a breast prosthesis comprised of an inner and outer lumen each with self-sealing valves with removable fluid filling tube(s).

(h) Bonnar—Patent No. 3,646,929

Issued March 7, 1972 on "Female Incontinence Device"

This patent describes a device comprising a balloon which is expandable via a connecting tubing attached to a reservoir. A valve is included along the tube for retaining fluid in the balloon. The balloon is inflated and deflated for use as a female incontinence device via the attached reservoir.

(i) Heimlich—Patent No. 3,672,372

Issued June 27, 1972 on "Urinary Drainage Method"

This patent describes a device useful for urinary drainage which comprises a flexible tubing attached at one end to an inflatable balloon and its other end to a valve.

(j) Hartley—Patent No. 3,934,274

Issued January 27, 1976 on "Deflatable Mammary Augmentation Prosthesis"

This patent describes a delayed adjustable mammary prosthesis comprising two sacs, one with an inlet opening with a normally closed valve through which a filling tube is detachably connected. The other end of the filling tube is designed for attachment to the end of a syringe or other liquid reservoir.

(k) Sanders—Patent No. 3,919,724

Issued November 18, 1975 on "Implantable Prosthesis Having a Self-Sealing Valve"

This patent describes a delayed filling breast implant with a valve in the wall of the prosthesis for a filling tube to detachably connect to the prosthesis for inflating the implant. One embodiment described by Figure 6 and lines 3-6 suggests a self-sealing filling site connected to a tube which can be penetrated by a needle in order to inflate a (balloon) cuff.

65. The references not before the Patent Office include certain publications of the applicant-patentee Becker relied on by the defendants at trial and include the following:

(a) "Breast Reconstruction Using an Inflatable Breast Implant with Detachable Reservoir" published in "Plastic and Reconstructive Surgery" for April, 1984. The publication indicates "received for publication December 9, 1982, revised June 27, 1983"; Exhibit 223. In this publication Dr. Becker evaluated his discovery on page 678 as follows:

"... the standard Heyer-Schulte type inflatable breast implant has been modified to enable a reservoir to be attached and detached at a side filling valve. The breast implant, therefore, functions initially as a tissue expander and then remains in position as a permanent once the reservoir is removed."

In this same publication, Dr. Becker stated on page 680 as follows:

"Since first described the inflatable breast implant has undergone several changes. Initially, the filling tubes were fixed to the implant, the newer implants now have selfsealing valves with detachable filling tubes by attaching a reservoir to the filling tube a regular inflatable breast implant is converted into a tissue expander."

On page 678, Dr. Becker states:

"Over a period of twenty months, twenty-five cases representing twenty-three patients with a total of thirty-four breasts have been operated on using this implant."

(b) "The Permanent Tissue Expander" published in "Clinics in Plastic Surgery," Vol. 14, No. 3, July, 1987, Exhibit 206.

As late as July, 1987, Dr. Becker was still publishing how he came about producing his Permanent Tissue Expander. On page 519 of Exhibit 206, he states as follows:

"This concept was initially achieved by attaching an injection dome to the free end of the filling tube that is commonly used to inflate a saline-inflatable implant."

(c) "Breast Reconstruction After Modified Radical Mastectomy," Southern Medical Journal, Vol. 75, No. 11, pages 1335-1338, November, 1982; note page 1337 in particular re the leakage problem of a single lumen saline fillable mammary implant; Exhibit 227.

66. During the pendency of the Becker patent application and after entering into the license agreement with Mentor recited in Finding No. 13, Mentor sought approval for sale of a reverse double lumen, delayed filling implant from the Federal Drug Administration (FDA), Exhibit 276. The FDA submission identified and discussed the prior art devices and equivalency. None of this prior art was made of record in the Becker patent application record and was not considered by the patent examiner. This was relied on by the defendants at the trial.

67. The Mentor submission to the FDA included a reference to a publication of Drs. Birnbaum and Olsen entitled "Breast Reconstruction Following Radical Mastectomy Using Custom Designed Implants." Plastic and Reconstructive Surgery, 61:3, pages 355-363, 1978; see page 8, reference 4 of Exhibit 276.

(a) The Mentor's FDA submission of December 5, 1984, on page 7, represented to the FDA the following:

"A method similar to that discussed in this submission was presented by Dr. Lawrence Birnbaum and Dr. John Olsen at the American Society for Aesthetic Plastic Surgery Annual Meeting in March, 1977.

Their series of 37 patients underwent breast reconstruction with inflatable implants serially expanded by the addition of saline. The implant was expanded over a period of several months until the desired volume is achieved. The inflatable implant either then remained in place as a permanent implant or was exchanged for a gel prosthesis."

(b) On pages 4-6 of Mentor's December, 1984, submission, they disclosed the equivalent devices that were marketed prior to May 28, 1976. On pages 5 and 6, fifteen "equivalent prostheses" that were currently manufactured and marketed were listed. This listing included the Gel-Saline Filled Reverse Double Lumen Mammary Prosthesis of Cox-Uphoff International. In summarizing the equivalence on page 6 of Exhibit 276, Mentor represented to the FDA as follows:

"The Mentor Expander Mammary Prosthesis shares specific design characteristics and components with several of the above referenced devices. The reverse-double lumen design of an inflatable saline-filled envelope surrounded by a gel outer lumen is currently marketed by Cox-Uphoff International (#8 above). The valve used in the Mentor Expander Mammary Prosthesis is the retention valve currently being used in the Mentor Inflatable Mammary Prostheses (#1 above). The reservoir and tubing connections used for expanding the prosthesis are the same as those used in the Mentor Radovan Tissue Expander (#7 above). The valve through the gel portion of the implant is similar in design to the Surgitek[®] Gel/Saline Mammary Implant (#11 above), in which saline is injected into the silicone gel."

68. Dr. Becker admitted at trial that he had knowledge of the Birnbaum-Olsen publication of Finding No. 67, but did not call the patent examiner's attention to it since he was

of the opinion that it was equivalent to the Lake U.S. patent 4,095,295, which he did call to the Examiner's attention.

69. Dr. Becker did not disclose to the patent examiner his prior knowledge of the fact that single lumen implants leak. A single lumen, saline fillable implant is the only embodiment disclosed in the '733 patent; see Exhibit 227 recited in Finding No. 65(c). Dr. Becker had knowledge of the leakage problem per his publication recited in Finding No. 65(c).

70. After experiencing deflation problems with his single lumen device, Dr. Becker sought the aid of the defendants for solving the deflation problem. Dr. Becker discussed the problem with Cox-Uphoff's president, and he suggested a solution through the use of the Cox-Uphoff reverse double lumen implant; Exhibits 36, 50, 234 and 235. Mentor commercialized the Becker concept in terms of a reverse, double lumen implant.

Prior Art, Contrasted to the Claims of the 4,643,733 Patent

71. The prior art Radovan et al '889 patent identically discloses the subject matter of Becker patent claim 1, except for the language added by amendment, namely, the prosthesis being "constructed substantially entirely of a relatively soft and flexible material" and the inlet opening for the prosthesis forming a relatively smooth exterior surface upon detachment of the filling tube.

72. The amendatory material referred to in Finding No. 71 is identically disclosed in the Heyer-Schulte Inflatable Mammary Prosthesis, which was admitted by Becker in the PTO to be prior art and is so described in column 1, lines 50-62, of the '733 patent.

73. The publication of Dr. Becker referred to in Finding 65(a), page 678, of Exhibit 223 is an admission by Dr. Becker that his patent claim 1 is descriptive of the "standard Heyer-Schulte type" implant of the acknowledged prior art that has

a means of injecting the saline solution into the implant by way of "a reservoir" of the type disclosed by Heyer-Schulte (a syringe). The original Becker publication was submitted for publication in December, 1982, and revised on June 27, 1983, shortly after filing his application in the PTO.

74. As late as July, 1987, immediately prior to commencement of the litigation, Dr. Becker was still publishing how he came about producing his Permanent Tissue Expander referred to in Finding No. 65(b). In that publication, Dr. Becker admitted he attached "an injection dome to the free end of the filling tube" of the prior art implant; page 516 of Exhibit 206.

The Level of Ordinary Skill in the Art

75. To design a delayed filling implant of the type disclosed in the Becker '733 patent based on the technology of the prior art disclosures would require the level of skill associated with a medical doctor practicing tissue expansion and breast reconstruction. These practices were common to plastic surgeons in the late 1970's.

The Obviousness of the 4,643,733 Patent

76. The known, acknowledged prior art inflatable breast implant manufactured by Heyer-Schulte was admitted to be the implant that was modified by Dr. Becker in his publications to provide delayed filling so that the Heyer-Schulte implant could function as a tissue expander and remain in position as a permanent implant. Dr. Becker merely substituted a prior art "reservoir" of the type disclosed in the Radovan '889 patent for a prior art "reservoir" in the form of a syringe to permit "delayed filling."

77. The patent examiner apparently overlooked his original analysis of the Becker patent application claims as representing a combination of the teachings of the Heyer-Schulte implant in combination with the Radovan '889 patent when

he considered the amended patent claims to overcome the rejection on the basis of Radovan alone. The original analysis of the examiner and his rejection of the claims was correct and should have been reconsidered and the claims rejected.

78. In addition to Radovan, the prior art Berson U.S. patent 4,246,893, Exhibit 257, disclosed a permanent implant with augmentation or reduction by percutaneous injection or removal of fluid by means of a subcutaneously implanted reservoir. The Berson device included a reservoir, fill tube and prosthesis made of a relatively soft and flexible material. The fill tube of Berson was not detachable from the prosthesis as disclosed.

79. The Birnbaum-Olsen publication of Finding No. 67 established the use of a single implant that is left in the body permanently after expansion, contrary to Dr. Coffee's understanding, prior to Becker.

80. In Dr. Becker's publication referred to in Finding No. 65(a) (Exhibit 223), it was indicated as being revised for the last time on June 27, 1983, less than four months after the Becker filing date. This publication was an admission by Dr. Becker of the commercial usage of his invention more than one year prior to the filing of his patent application.

CONCLUSIONS OF LAW

1. This is a patent suit brought under the patent laws of the United States, 35 U.S.C. ¶s 1-293. The Court has jurisdiction of the parties and of the subject matter of this action by virtue of 28 U.S.C. ¶s 1338 and 2201. There is an actual controversy between the parties concerning the subject matter of this action; 28 U.S.C. 2201. Further, the Court has determined that venue is properly laid in this district under 28 U.S.C. 1400(b).

2. Plaintiffs, Mentor, have the burden of establishing by a preponderance of evidence that Cox-Uphoff's products

have infringed the claims of either the '889 and/or the '733 patents.

3. Defendant Cox-Uphoff, have the burden of establishing invalidity or unenforceability of the claims of the '889 and/or the '733 patents. A patent is presumed to be valid pursuant to 35 U.S.C. 282.

4. The grant of a patent by the U.S. Patent and Trade-mark Office bears a presumption of validity as to prior art considered by the Patent Office. The burden of establishing invalidity on the party asserting it is an important aspect of the validity of a patent in suit and cannot be overlooked by a Court; *Solder Removal Company et al vs. U.S. International Trade Commission et al* 582 F. 2d 628, 632-633, 199 USPQ 129, 133, see notes 8, 9 and 10; *TP Laboratories, Inc. v. Professional Positioners, Inc.* 724 F. 2d 965, 220 USPQ 577 (Fed. Cir. 1984); *Stratoflex, Inc. v. Aeroquip Corp.* 713 F. 2d 1530, 218 USPQ 871, 875, 876 (Fed. Cir. 1983).

5. The defense of lack of novelty or anticipation can only be established by a single prior art reference which discloses each and every element of the claimed invention. Anticipation is not shown even if the differences between the claims and the prior art reference are "insubstantial" and the missing elements could be supplied by the knowledge of one skilled in the art. *Structural Rubber Products Co. v. Park Rubber Co.* 749 F. 2d 707, 223 USPQ 1264, 1270 (citing cases).

6. Under 35 U.S.C. 103 in order for a patent to be granted by the Patent Office, the difference between the subject matter sought to be patented and the prior art must be such that the subject matter as a whole would not have been obvious at the time the invention was made to a person with ordinary skill in the art.

The statutory conditions of 35 U.S.C. 103 have been considered by the United States Supreme Court and the Court has established that certain factual inquiries need to

be made when there is no identity between the prior art and the claimed invention for evaluation of the statutory conditions that must be satisfied to render a patent valid. *In Graham v. John Deere Co.* 383 U.S. 1, 17, 15 L.ed. 2d 545, 86 S. Ct. 684, 148 USPQ 459, 466, 467, the Court indicated on page 17 of 383 U.S. 1, that the inquiries should be:

"1. The scope and content of the prior art are to be determined.

"2. The differences between the prior art and the claims in issue are to be ascertained.

"3. The level of the ordinary skill in the pertinent art resolved."

As the Court indicated against this background, which is a factual background, the obviousness or nonobviousness of the subject matter is determined. The Court also indicated that the secondary considerations, such as commercial success, long felt but unsolved need, failure of others, etc., have relevancy as to "nonobviousness".

7. The "subject matter as a whole" refers to the subject matter of each and every claims as a whole and not to the individual elements of a claimed combination and their individual novelty. *Stratoflex, Inc. v. Aeroquip Crp.* 713 F. 2d 1530, 218 USPQ 871 (Fed. Cir. 1983); *Jones v. Hardy* 727 F. 2d 1524, 220 USPQ 1021, 1024 (Fed. Cir. 1984).

8. The Court of Appeals for the Federal Circuit has ruled that these "secondary considerations" in *Graham* must always be considered before reaching a conclusion under 35 U.S.C. 103; *In re Sernaker*, 702 F. 2d 989, 217 USPQ 1 (CAFC 1983).

9. The scope of the prior art relative to a patented invention has been defined by the Court of Customs and Patent Appeals (CCPA) as that "reasonably pertinent" to the particular problem with which the inventor was involved. *In re Wood* 559 F.2d 1032, 1036, 202 USPQ 171, 174 (CCPA

1979); *Stratoflex, Inc. v. Aeroquip Corp.* 713 F. 2d 1530, 218 USPQ 871, 876 (Fed. Cir. 1983).

10. The legal tests concerning the evaluation of the level of ordinary skill in the art under 35 U.S.C. 103 is determined by evaluating the various prior art approaches employed, the sophistication of the technology involved, and the educational background of the workers in the art in accordance with *Orthopedic Equipment Co., Inc. v. All Orthopedic Appliances, Inc.* 707 F. 2d 1376, 217 USPQ 1281, 1285 (Fed. Cir. 1983).

The educational background of the inventor of the patent in suit is not a consideration. *Environmental Designs, Ltd. v. Union Oil Co. of California* 713 F. 2d 693, 218 USPQ 865, 868, 869 (Fed. Cir. 1983).

11. Obviousness cannot be established under 35 U.S.C. 103 when there are no teachings or suggestions supporting a claimed combination. *ACS Hospital Systems, Inc. v. Montefiore Hospital* 732 F. 2d 1572, 221 USPQ 929, 933 (Fed. Cir. 1984).

The "subject matter as a whole" of a claimed combination must be evaluated to render a judgment of obviousness or nonobviousness; see *Stratoflex, Inc.*, *Supra*.

Radovan '889 Patent

12. On the basis of the Findings of Fact entered herein, the Court has concluded that Cox-Uphoff has not proved by clear and convincing evidence facts compelling a conclusion of patent invalidity of claims 23-27, 29, 30 and 31 of the '889 patent. Specifically, the Court has considered the presumption of validity, 35 U.S.C. 282, and the evidence on invalidity adduced at trial, and concluded that the subject matter of the patent claims would not have been obvious to one skilled in the art at the time of the application for the '889 patent within the meaning of 35 U.S.C. 103.

13. The claims of the '889 patent must be construed the same for both infringement and validity, *SRI International v. Matsushita Electric Corp. of America*, 775 F.2d 1107, 1121, 227 USPQ 577, 585 (Fed. Cir. 1985).

14. In determining whether a device infringes a patent claim, resort must be had in the first instance to the words of the claim. If the accused device falls clearly outside of the scope of a patent claim or any equivalents, correctly interpreted, there is no infringement. *Graver Tank Mfg. Co., Inc. v. Linde Air Products Co.*, 339 U.S. 605, 607, 608 (1950) 85 USPQ 328, 330. Each element of a patent claim must be found in an accused device to support a claim of infringement. *Lemelson v. United States*, 752 F.2d 1538, 1551, 224 USPQ 526, 532-533 (Fed. Cir. 1984).

15. In light of the Findings of Fact entered herein, the Court has concluded that the Cox-Uphoff "backed" "Versafil" tissue expanders do not infringe within the meaning of 35 U.S.C. 271, any one of claims 23-27, 29-31 of the Radovan et al patent '889. Mentor presented no proofs of infringement of a properly interpreted patent claim. *Fonar Corp. v. Johnson and Johnson*, 821 F.2d 627, 631-633; 3 USPQ 2d 1109, 1112-1113 (Fed. Cir. 1987).

16. Cox-Uphoff is entitled to a Judgment in its favor as to the '889 patent, and its costs.

Becker '733 Patent

17. The proofs and evidence adduced at trial establishes that the defendant has met its burden of proving by clear and convincing evidence of the facts establishing invalidity of the Becker '733 patent, pursuant to 35 U.S.C. 282. *Panduit Corp. v. Dennison Mfg. Co.*, 774 F.2d 1082, 227 USPQ 337, 346-347 (Fed. Cir. 1985).

18. On the basis of the Findings of Fact entered herein, the Court has concluded that claims 1-4, 7 and 8 of the Becker '733 patent are invalid, pursuant to 35 U.S.C. 103.

Specifically, the Court has concluded that the admissions of Dr. Hilton Becker in evaluating his discovery reveals that the modification of the standard Heyer-Schulte inflatable breast implant, in attaching the prior art type of reservoir or dome as a substitute for the prior art reservoir in the form of a syringe, is a substitution suggested and disclosed in the Radovan et al '889 patent, or Berson '893 patent, so that it was within the skill of the workers in the art, immediately prior to the filing of the Becker patent application in the Patent and Trademark Office, to substitute one known form of reservoir for another known form of reservoir and, therefore, the subject matter of the Becker patent claims, taken as a whole, was obvious and invalid under 35 U.S.C. 103.

19. The U.S. Patent and Trademark Office is not authorized to issue patents whose effects are to remove existent knowledge from the public domain or to restrict free access to materials already available. *Graham v. John Deere Co.*, 383 U.S. 1, 6, 86 S. Ct. 684 (1966).

20. The conditions for patentability recited in 35 U.S.C. 102 include the loss of right to a patent if an invention was in public use in this country more than one year prior to the date of application for patent in the United States (see (b) of 35 U.S.C. 102).

21. In light of the Findings of Fact entered herein, the Court has concluded that the subject matter of the claims of the '733 patent was in public use by Dr. Becker for more than one year prior to the filing of the Becker patent application in the Patent and Trademark Office, based upon Dr. Becker's admissions in his publication so stating and, therefore, the patent claims are invalid.

22. If any Finding of Fact is construed as a Conclusion of Law, or any Conclusion of Law herein is construed as a Finding of Fact, the same is deemed to be such.

DATED: February 27, 1989

JESSE W. CURTIS

Jesse W. Curtis
United States District Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA

MENTOR CORPORATION, *et al.*,

Plaintiffs.

v.

COX-UPHOFF CORPORATION.

Defendant.

No. CV 87-5611-JWC(Tx)

JUDGMENT

In accordance with the foregoing Findings of Fact and Conclusions of Law, it is ordered, adjudged, and decreed as follows:

1. That this Court has jurisdiction of the subject matter and of the plaintiffs and defendant.

2. That plaintiffs are the owners of all right, title and interest in, to and under the Letters Patent of the United States Nos. 4,217,889 and 4,643,733.

3. That Letters Patent No. 4,217,889 and each and every claim 23-27, 29-31 thereof are not invalid in law.

4. That Letters Patent No. 4,217,889 and none of the claims 23-27, 29-31 have been infringed by the defendant.

5. That Letters Patent 4,643,733 and each and every claim 1-4 and 7-8 is invalid under 35 U.S.C. 103 and unenforceable.

6. That the subject matter of Letters Patent 4,643,733 was in public use more than one year prior to the filing of the application for Letters Patent and therefore is barred under 35 U.S.C. 102 whereby each and every claim thereof is invalid and unenforceable.

7. That the Complaint for infringement of Letters Patent Nos. 4,217,889 and 4,643,733 is hereby dismissed as to defendant Cox-Uphoff Corporation.

8. That defendant Cox-Uphoff Corporation shall recover its taxable costs herein from plaintiffs in the sum of \$

9. That pursuant to defendant Cox-Uphoff Corporation's counterclaim it is hereby decreed:

a. That U.S. Letters Patent 4,217,899 and 4,643,733 and each and every claim of each are invalid, void and unenforceable.

b. That the patents in suit are not infringed by any device, made, used or sold by counterclaimant

DATED: February 27, 1989

JESSE W. CURTIS

Jesse W. Curtis

United States District Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA

MENTOR CORPORATION, <i>et al.</i> , <div style="text-align: center;"><i>Plaintiffs.</i></div> <div style="text-align: center;">v.</div> COX-UPHOFF CORPORATION, <div style="text-align: center;"><i>Defendant.</i></div>	} }	NO. CV 87-5611-JWC(Tx) MEMORANDUM AND ORDER DENYING DEFENDANT'S MOTION TO AMEND FINDINGS OF FACT, CONCLUSIONS OF LAW AND JUDGMENT, etc.
--	--------------------------------	---

The defendant moves for an order establishing that the Becker Patent in suit was obtained by inequitable conduct before the Patent and Trademark Office; for additional findings of fact and conclusions of law establishing the "exceptional" nature of this litigation, and for the award of attorneys' fees.

Plaintiffs challenge the motion, arguing that this court is without jurisdiction to consider the motion as it is untimely. Federal Rules of Civil Procedure 52(b) and 59(e) both require a party requesting additional findings or an amended judgment to make its motion not later than ten days after the entry of judgment. It appears that this precise question has been submitted to the court of appeals for the federal circuit which has ruled against the defendant, but the matter is still before the court on a motion for rehearing filed by the defendant. This being so, I do not consider it a proper issue to be considered here.

However, even assuming the motion to be timely, it is without merit and must be denied.

Cox-Uphoff contends that there is convincing evidence that the Becker Patent was obtained by inequitable conduct. This, he asserts, was accomplished by Becker making certain alterations on his patent application after its execution but before it was filed in the Patent Office contrary to 37 C.F.R. 1.56(c)(4).

In my view, "execution" involves more than merely signing a patent application. Like a deed where delivery is required, the "execution" of a patent application requires more than merely signing the document. There should be some act beyond that indicating an intent to irretrievably send it on its way to the Patent Office. I find no such evidence in this case which would justify a finding that there was a material alteration of the patent application after it was executed. Furthermore, I find no clear and convincing evidence that the patent failed to disclose material information, or that the patent intentionally withheld pertinent information which the Patent Office should have had.

Cox-Uphoff, in this motion, further moves the court for an order declaring this to be an exceptional case justifying the award of reasonable attorneys' fees pursuant to 35 U.S.C. § 285. The purpose of this section in awarding attorneys' fees in exexceptional cases contemplates such misconduct on the part of a losing party as to constitute fraud on the Patent Office, or so unfair and reckless as to make it unconscionable for the prevailing party to sustain the expense of counsel. *Q-Panel Co. v. Newfield*, 482 F.2d 210 (10th Cir. 1973). I find no such evidence as would justify the award of attorneys' fees in this case.

If it is subsequently determined that this court has jurisdiction to do so, and in the event of a reversal of this court's judgment N.O.V. on appeal, the defendant's motion for a new trial is granted on the ground that the verdict is contrary to the substantial weight of the evidence and that the award of damages is excessive.

DATED: April 24, 1989

JESSE W. CURTIS

Jesse W. Curtis
United States District Judge

**United States Court of Appeals
for the Federal Circuit**

89-1302.-1348.-1472

MENTOR CORPORATION,
LINDA RADOVAN WILLIAMSON,
as executrix of the Estate of CHEDOMIR RADOVAN;
HILTON BECKER, M.D.; AND
BEVERLEY ANNE BECKER,

Plaintiffs-Appellants,

v.

COX-UPHOFF CORPORATION AND
COX-UPHOFF INTERNATIONAL.

Defendants/Cross-Appellants.

Judgment

ON APPEAL from the
in CASE NO(S).

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
87-5611 JWC

*This CAUSE having been heard and considered,
it is ORDERED and ADJUDGED:*

**REVERSED, REMANDED,
VACATED, AND DISMISSED**

ENTERED BY ORDER OF THE COURT

DATED: Nov. 9, 1989

FRANCIS X. GINDHART

Francis X. Gindhart, Clerk

ISSUED AS A MANDATE: DECEMBER 21, 1989
COSTS: AGAINST CROSS-APPELLANTS

Printing.....\$970.93

Total\$970.93

United States Court of Appeals
for the Federal Circuit

89-1302, -1348, -1472

MENTOR CORPORATION,
LINDA RADOVAN WILLIAMSON,
as executrix of the Estate of CHEDOMIR RADOVAN;
HILTON BECKER, M.D.; AND
BEVERLY ANNE BECKER,

Plaintiffs-Appellants.

v.

COX-UPHOFF CORPORATION AND
COX-UPHOFF INTERNATIONAL,

Defendants/Cross-Appellants.

ORDER

ORDER

Before RICH, Circuit Judge, MAYER, Circuit Judge, and MICHEL, Circuit Judge.

A petition for rehearing having been filed in this case, UPON CONSIDERATION THEREOF, it is ORDERED that the petition for rehearing be, and the same hereby is, denied.

The suggestion for rehearing in banc is under consideration.

The mandate will issue on December 21, 1989.

FOR THE COURT,

FRANCIS X. GINDHART

Francis X. Gindhart
Clerk

Dated: December 14, 1989

cc: ALAN M. ANDERSON
EDWARD J. DARIN
ARTHUR A. OLSON, JR.

MENTOR CORP V COX-UPHOFF, 89-1302, -1348 & -1472

<p>Note: This order has not been prepared for publication in a reporter.</p>
--

A-55

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT
717 MADISON PLACE, N.W.
WASHINGTON, D.C. 20439

FRANCIS X. GINDHART
CLERK

TELEPHONE 633-6999
AREA CODE 202

December 15, 1989

Alan M. Anderson, Esq.
Faegre & Benson
2200 N.W. Center
90 S. Seventh Street
Minneapolis, MN 55402

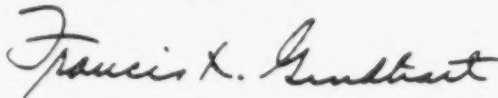
Re: Mentor Corp v. Cox-Uphoff, No. 89-1302, -1348 &
-1472

Dear Mr. Anderson:

The court has requested a response from appellants to cross-appellants' Suggestion for Rehearing In Banc.

Please file your response in accordance with Federal Circuit Rule 35 on or before December 26, 1989.

Very truly yours,



Francis X. Gindhart

FXG:ld

cc: Edward J. Darin
Arthur A. Olson, Jr.

United States Court of Appeals
for the Federal Circuit

89-1302, -1348, -1472

MENTOR CORPORATION,
LINDA RADOVAN WILLIAMSON,
as executrix of the Estate of CHEDOMIR RADOVAN;
HILTON BECKER, M.D.; AND
BEVERLY ANNE BECKER,

Plaintiffs-Appellants,

v.

COX-UPHOFF CORPORATION AND
COX-UPHOFF INTERNATIONAL,

Defendants/Cross-Appellants.

ORDER

ORDER

A suggestion for rehearing in banc having been filed in this case, and a response thereto having been invited by the court and filed,

UPON CONSIDERATION THEREOF, it is

ORDERED that the suggestion for rehearing in banc be, and the same hereby is, declined.

Judge Nies, Judge Bissell and Judge Archer would rehear the case in banc.

FOR THE COURT

Dated: January 8, 1990

FRANCIS X. GINDHART

Francis X. Gindhart
Clerk

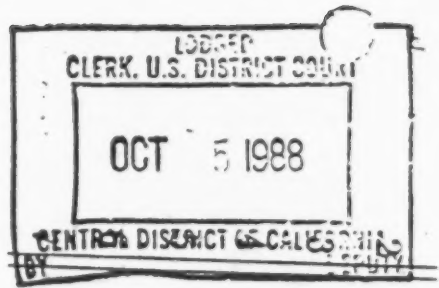
cc: Alan M. Anderson
Edward J. Darin
Arthur A. Olson, Jr.

MENTOR CORP V COX-UPHOFF, 89-1302
DCT—87-5611 JWC

Note: This order has not been prepared for publication in a reporter.

EDWARD J. DaRIN
EDWARD J. DaRIN, INC.
301 East Colorado Blvd.
Suite 518
Pasadena, CA 91101
Tel. (818) 793-0689

Attorney for Defendants



IN THE UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

MENTOR CORPORATION, *et al.*
Plaintiffs.

v.

COX-UPHOFF CORPORATION,
et al.
Defendants.

Civil Action No. 87-05611 JWC
MOTION FOR JUDGMENT
NOTWITHSTANDING
THE VERDICT AND
ALTERNATIVE MOTION
FOR NEW TRIAL BY
DEFENDANTS PER
F.R.CIV.P.50(b)
Hearing Date: Nov. 14, 1988
Time: 10:00 A.M.

Defendants move the Court to set aside the verdict entered in the above action on September 23, 1988 and the Judgment entered on October 4, 1988, and to enter Judgment in favor of the defendants pursuant to the Motion of the defendants for a directed verdict. The Motion of the defendants for directed verdict should have been granted based on the following grounds:

1. The evidence in the case showed conclusively that the claims of U.S. patent 4,217,889 granted on August 19, 1980 in the name of Radovan, et al. are invalid under 35 U.S.C. 103, when the subject matter of the claims are taken as a whole.

2. The evidence in the case showed conclusively that the defendants' "Versafil" backed tissue expanders were not infringements of apparatus claims 23 through 27, 29, and method claims 30 and 31 of said Radovan et al patent, and the claims cannot be validly expanded to cover the defendants' products, based on the prosecution history estoppel and/or the reverse doctrine of equivalents.

3. The plaintiffs' relied on the presumption of validity (35 U.S.C. 282) and no evidence was presented by the plaintiffs on the issue of validity as to both the patents in suit, including the rebuttal of the defendants' invalidating evidence. Therefore, the evidence does not establish that plaintiffs are resorting to the same interpretation of the claims of the Radovan et al '889 and Becker '733 patents for both validity and infringement purposes, as the law requires.

4. In furtherance of the grounds detailed as to lack of infringement, the trial evidence and the trial testimony of the plaintiffs' witnesses establish a lack of complete understanding of the operation of the defendant's "Versafil" backed tissue expanders and the correct sealing action in the lumens of each of the two different designs of the defendant's RDL-Xpand mammary prosthesis, whereby to negate the jury verdicts on infringement of the Radovan et al and Becker patents and any claim of willful infringement.

5. The evidence in the case conclusively established that the Claims of the Becker patent 4,643,733, granted on February 17, 1987, are invalid under U.S.C. 103, based on either the prior art (1) before the Patent Office, and/or (2) the prior art not considered by the Patent Office (i.e. Berson patent 4,246,893, Exhibit 257) when the subject matter of each of the claims is taken as a whole.

6. The evidence in the case showed conclusively that apparatus claim 1 through 4, 7 and method claim 8, were not infringed by either design of the defendants' expandable mammary prosthesis identified as the "RDL-Xpand". The

Becker patent claims cannot be expanded to cover the defendants' products, as the products are not equivalent to the patented structures and basically are in the public domain and not the patentee's invention. The reverse double lumen construction of each of the defendant's products and the sealing of each lumen upon withdrawal of the filling tube by means of the gel and/or plug is covered by the prior art, including the Boone '718 patent (Exhibit 248) and is outside the scope of the Becker patent claims.

7. Claims 30 and 31 of the Radovan et al patent 4,217,889, and claim 8 of the Becker patent 4,643,733, are all method claims and the evidence conclusively establishes that there was no literal infringement by the defendants of each of these claims. No jury instruction was given as to infringement of a patent claim based on contributory infringement or inducing infringement pursuant to 35 U.S.C. 271(b) or (c) and, therefore, the verdict is erroneous as not supported by the evidence and not in accordance with the law.

Becker—Inequitable Conduct

No verdict was returned by the jury on the inequitable conduct facts and having been discharged by the Court on September 23, 1988, defendants move this Court to enter judgment in accordance with the defendants' motion for directed verdict for inequitable conduct as to the Becker '733 patent, based on the trial evidence. The defense of inequitable conduct is an equitable defense to be evaluated solely by the Court and is not a jury issue: *Gardco Mfg. v. Herst Lighting Co.* 820 F. 2d 1209, 1211-1213, 2 USPQ 2d 2015, 2017-2019 (Fed. Cir. 1987). Under this ruling, a patent(s) may be valid and yet unenforceable as to all of the claims of the patent claims for inequitable conduct and, therefore, may be dispositive of the merits of the Becker patent, which issue is distinct from the issues of validity and infringement.

No evidence was submitted by the plaintiffs to negate or rebut the defendants' inequitable conduct evidence and the patentee's testimony of his knowledge of material, undisclosed prior knowledge and prior art, and his review of all of the papers filed in the Patent office by his counsel fortifies the defendants' evidence of inequitable conduct before the Patent Office and the attempt to improperly enforce the invalid and/or unenforceable patent in this Court.

The patentee's first act of serious misconduct was to file his marked-up patent application which was altered and amended after execution of the declaration for the application. The materiality of the alterations and amendments in the filed application are revealed by comparing the unmarked copy of the Becker application, Exhibit 219, with the altered filed copy of the patent application in Exhibit 140.

In addition, Becker's trial testimony and his publications (i.e., Exhibit 223, pages 678, column 1, second paragraph) identify the simple change to be made to the Heyer-Schulte type inflatable breast implant that was never disclosed in such simple terms in either his patent application or the record before the patent office.

The patentee and his attorney, despite acknowledging certain prior art, sought patent claims identical to the known prior art (Radovan patent) and obtained patent claims descriptive of the known prior art of record in the Becker patent application (namely the Heyer-Schulte and Dow Corning implants of record in Exhibit 140) and accompanied by misleading arguments in the Patent Office as to the problems of the prior art structures, contrary to the knowledge of the prior art of Mentor and the patentee.

The claims allowed by the patent examiner were erroneously granted over the teachings in the Radovan patent alone without consideration by either the patent examiner or Becker's patent counsel of the prior art of record in the Becker application, as well as other prior art known to Becker at the

time. Becker knew, or should have known, that the changes adopted to distinguish over the Radovan prior art of record were insufficient for defining patentable subject matter.

A large volume of prior art is found in Mentor's representations to the Federal Drug Administration (FDA), per Exhibit 276, as to prior art and equivalency, which is totally absent from the record in the Becker file wrapper and, therefore, was not considered by the patent examiner.

There can be no issue as to the materiality of the wealth of uncited, known prior art and of the gross negligence of Becker, his patent counsel and Mentor, in not making this prior art of record for evaluation by the patent examiner.

New Trial

In the alternative, defendants move the Court to set aside the verdict and the judgment entered thereon and grant the defendants a new trial on the following grounds:

1. The verdict is contrary to law and the Court's instructions thereon as to damages.

2. The verdict as to validity and infringement of the patents is contrary to the weight of the evidence, as noted hereinabove.

3. The verdict of the jury as to damages is grossly excessive and unreasonable under the evidence and contrary to law and was determined under the influence of passion or prejudice.

4. The verdict of the jury as to willful infringement is contrary to law as there is no evidence of copying either product. The defendants' flat tissue expanders are completely structurally distinct from the patented product and noninfringing. The defendants' original mammary prosthesis was developed based on defendants' own products and the state of the art long before the grant of the Becker patent in February, 1987.

5. The sums awarded in the jury verdict are essentially sums for lost profits offered by Mentor and include sums for prejudgment interest. The inclusion of prejudgment interest in the damage award is erroneous as the award of prejudgment interest is solely within the discretion of the Court and not the jury. The inclusion of these sums is excessive and erroneous.

6. The award of lost profits is contrary to law [*Paper Converting Machine Co. v. Magna Graphics Corp.* 745 F.2d 11,21, 223 USPQ 591, 598] (Fed. Cir. 1984) since the evidence of both parties establishes that the market for the tissue expanders and mammary prosthesis was not a two-supplier market and the evidence does not establish, according to law, that the plaintiff would have made the sales made by Cox-Uphoff. The evidence also establishes the availability of a number of acceptable noninfringing substitutes for each of the products alleged to infringe to negate the award of damages based on lost profits as a whole.

7. The correct measure of damages, if any, should be based on a "reasonable royalty" under the law; 35 U.S.C. 284.

8. Damages are governed by 35 U.S.C. 284. The limitations on damages are governed by 35 U.S.C. 287. The jury award is clearly excessive since it ignores the fact that no evidence was presented to establish when Mentor's products were marked with the patent notice (or if the Mentor products are covered by the patent in suit) and no notice of infringement was received by the defendants of the Radovan et al patent prior to January, 1987, therefore, damages should not have been awarded prior to that time. The damage award further included an award of lost profits for the year 1985, at a time the defendants had not produced or sold an allegedly infringing tissue expander product. Similarly, the first notice of infringement of the Becker patent grant that Mentor provided the defendants was May, 1987, and the jury erro-

neously awarded damages commencing February 18, 1987, again, contrary to law.

9. The Mentor computation of damages is not sufficiently detailed to permit a determination of their correctness and are based on unwarranted assumptions, contrary to law and/or incomplete evidence.

10. In the event the defendants' motion notwithstanding the verdict is denied, consideration by the Court of the plaintiffs' remitting a portion of the damages verdict deemed excessive is also requested.

11. The closing argument by plaintiffs' counsel entitled defendant to a new trial for the following reasons:

(a) The plaintiffs' counsel's demonstrations of how the defendant's tissue expanders function by squeezing one of them in front of the jury was improper and misled the jury as to how the tissue expander functions.

(b) The directions of the plaintiff's counsel to the jury to examine an unidentified clinical text and the claim books, Exhibits 127 and 128, to establish infringement of three different products was erroneous, misleading and prejudicial since the claim books are vague and indefinite in merely directing attention to a part of defendant's products and concluding that the part numbered necessarily produces the function recited in the patent claim; i.e., in Exhibit 127 the counsel's conclusion as to the recited function of the base (3) in the exhibit is erroneous and prejudicial.

Exhibit 128 is apparently directed only to the new design of the defendant's mammary prosthesis, Exhibit 312A-C, which is significantly different in design from the design of the prior mammary prosthesis, Exhibit 310.

(c) The new mammary prosthesis (Exhibits 312A-C) was produced after the litigation commenced in an attempt to properly design around the Becker patent claims. The Exhibit erroneously and prejudicially equates the two prod-

ucts, including for purposes of willful infringement, whereby the jury was completely misled as to the construction and operation of the defendant's products and their relationship to the patent claims in issue.

(d) The claim book, Exhibit 128, is contrary to the evidence, including the testimony of the plaintiffs' patent law expert (which was also erroneous).

12. The plaintiffs' counsel's comments to the jury regarding the prior art were erroneous and prejudicial, and the comments were not relevant in stating and inferring that

(a) the device in the Berson patent 4,246,893 (not of record), Exhibit 257, was for use in the stomach and was not a breast implant and therefore was not the same thing;

(b) Dr. Becker considered the Birnbaum-Olson permanent expander, Exhibit 318, to be the same or the equivalent of the cited Lake patent 4,095,295, Exhibit 295, and therefore he need not tell the Patent Office about Birnbaum, although no evidence as to this position was ever filed in the Patent and Trademark Office or at any time prior to Becker's trial testimony. This misled the jury as to its patent validity determination as to the Becker patent and also should have been considered by Becker and Mentor as inequitable conduct, thereby misleading the jury and prejudicing the defendant; and

(c) the defendant's case should have included the testimony of surgeons, knowing such evidence is not necessary or necessarily competent.

13. This Honorable Court erred during the course of the trial in the following respects:

(a) In permitting the plaintiffs' patent law expert to testify as a technical expert contrary to the law and his qualifications, thereby misleading the jury and prejudicing the defendant.

(b) In permitting Dr. Becker to testify as a technical expert contrary to his qualifications, thereby misleading the jury to the defendant's prejudice.

Respectfully submitted,

EDWARD J. DaRIN, INC.

Date: Oct. 5, 1988

By EDWARD J. DaRIN
Edward J. DaRin
Attorney for Defendants

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of MOTION FOR JUDGMENT NOT WITHSTANDING THE VERDICT AND ALTERNATIVE MOTION FOR NEW TRIAL BY DEFENDANTS PER F.R.CIV.P. 50(b) of Defendant Cox-Uphoff was hand delivered by messenger, to counsel for Plaintiffs at the address indicated below on this 5th day of October 1988:

Michael R. Sullivan, Esq.
Sullivan, Walsh, Rossbacher & Wood
Biltmore Tower, 18th Floor
500 South Grand Avenue
Los Angeles, CA 90071

EDWARD J. DaRIN

Edward J. DaRin

EDWARD J. DaRIN
EDWARD J. DaRIN, INC.
Suite 518
301 E. Colorado Blvd.
Pasadena, CA 91101
(818) 793-0689
Attorney for Defendant

IN THE UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

MENTOR CORPORATION, *et al.*
Plaintiffs.

vs.

COX-UPHOFF CORPORATION,
Defendant.

Civil Action No. 87-5611 JWC (Tx)

DEFENDANT'S MOTION TO
AMEND THE FINDINGS
OF FACT, CONCLUSIONS
OF LAW, AND JUDGMENT
AND FOR ATTORNEY'S
FEES; MEMORANDUM OF
POINTS AND AUTHORITIES

Hearing Date: April 10, 1989

Time : 10:00 A.M.

The defendant, Cox-Uphoff Corporation, moves this Court for an ORDER amending the Findings of Fact, Conclusions of Law and Judgment entered in this action on February 28, 1989, and for an award of attorney's fees in the defendant's favor.

The requested ORDER includes an ORDER finally disposing of the issue of inequitable conduct before the Patent and Trademark Office relative to the Becker patent 4,643,733 pursuant to Federal Rule of Civil Procedure 49(a). The issue of inequitable conduct was tried, but no jury verdict was

rendered thereon and, therefore, the jury right has been waived and is now ripe for decision pursuant to Rule 49(a).

The Motion comprehends a request for amending the Findings of Fact, Conclusions of Law and Judgment in accordance with any additional finding and Conclusions of Law pursuant to Federal Rules of Civil Procedure 52(b) and 59(e). The requested additional findings are directed to the factual basis establishing that this litigation is "exceptional" within the meaning of 35 USC 285 required for an award of attorney's fees pursuant to said patent statute governing an award of attorney's fees in patent litigation. The Motion is directed to the infringement claim made on the basis of the Radovan et al U.S. patent 4,217,889 and the Becker patent 4,643,733 individually and collectively. It is clear that a finding or conclusion that the Becker patent was obtained by inequitable conduct entitles the defendant to its attorney's fees for defending against the Becker patent.

The Motion is also directed to correcting the Judgment as to the invalidity of the Radovan et al patent so as to conform it to the Court's Conclusions of Law in ¶9(a) and ¶13 of the Judgment. Also a conclusion of inequitable conduct as to the Becker patent would render each and every patent claim thereof unenforceable.

WHEREFORE the defendant moves for an ORDER establishing that the Becker patent in suit was obtained by inequitable conduct before the Patent and Trademark Office accompanied with additional Findings of Fact and Conclusion of Law establishing the "exceptional" nature of this litigation and an award of attorney's fees pursuant to 35 USC 285 and the amendment of the Judgment as requested and in conformance with any additional findings and/or Conclusions of Law. In the event of an award of attorney's fees in favor of the defendant, it is requested that this Court reserve jurisdiction of the litigation to permit the defendant to produce the required documentation for establishing the mone-

tary amounts of attorney's fees and expenses for the purposes of the award.

The present Motion is based on the aforementioned Federal Rules, 35 USC 285 and the attached Memorandum of Points and Authorities.

MEMORANDUM OF POINTS AND AUTHORITIES

Introduction

Certain Findings of Fact and Conclusions of Law were entered in this litigation, along with a Judgment, on February 28, 1989. This Court has ruled that the Radovan et al U.S. patent 4,217,889 is not invalid but is not infringed by the Versafil devices manufactured and sold by the defendant, the Cox-Uphoff Corporation, and that the Becker U.S. patent 4,643,733 was invalid and unenforceable. The Court rulings resulted from the granting of the defendant's Motion for Judgment N.O.V. relative to the jury verdict on patent validity and infringement.

One of the issues tried to the jury is whether the Becker '733 patent was obtained as a result of inequitable conduct before the Patent and Trademark Office. No verdict was returned by the jury on the inequitable conduct facts presented to them as no interrogatory was presented to them on this issue. The Court's Findings of Fact include facts which form a basis for a claim of inequitable conduct, if not a Conclusion of Law, on behalf of the defendant.

The issue of inequitable conduct has been ruled on by the Court of Appeals for the Federal Circuit as an equitable issue and may be evaluated solely by a court pursuant to the Federal Circuit's decision in *Gardco Mfg. v. Herst Lighting Company* 820 F.2d 1209, 1211, 1213, 2 USPQ 2d 2015, 2017-2019 (Fed. Cir. 1987). This position has been reaffirmed by the Federal Circuit in its recent decision of *Kingsdown*

Medical v. Hollister, Inc. 9 USPQ 2d 1384 (no Fed. cite) (Fed. Cir. Dec. 21, 1988). In the *Kingsdown Medical* decision, the Federal Circuit in an *in banc* decision clarified the law of inequitable conduct and specifically the intent element of inequitable conduct that should be controlling. Plaintiffs, Mentor, had requested the jury trial, including on this unresolved issue, and it now appears that it has waived its right for a jury verdict on inequitable conduct. No positive ruling resolving the inequitable conduct issue has been made, although the defendant moved the Court at the trial to enter such a Judgment in accordance with its Motion for directed verdict as to the Becker '733 patent. Federal Rule of Civil Procedure 49(a) authorizes the Court to make a finding on this issue that is now considered to have been waived as a jury issue. Plaintiffs have appealed and will re-appeal, making it important that the Court rule on this issue at the present time.

In addition, as a result of this Court's detailed entry of Findings of Fact and Conclusions of Law, issues that are within this Court's discretion as to whether the defendant is entitled to its attorney's fees as the prevailing party pursuant to 35 USC 285, is now timely.¹

The defendant submits that the facts required for resolving these issues are not in dispute, i.e., Becker's admissions (as noted in the Court's findings), but merely require the application of the law to the undisputed facts at this time.

Amendment of Findings of Fact and Conclusions of Law

The defendant submits that the request for additional Findings of Fact and Conclusions of Law and the amendment of the Judgment may be made pursuant to Federal Rules of Civil Procedure 52(b) and 59(e) and are proper in this case,

¹ In the defendant's submission of Proposed Findings of Fact and Conclusions of Law, this Court has eliminated the proposed Facts and/or Conclusions with respect to inequitable conduct and attorney's fees.

since they are merely amplifications of certain Findings of Fact previously made by this Court, and the requested amendments are not in conflict with them and have no reference to the facts found by the jury as they are matters solely within this Court's discretion and judgment; *Kardon v. National Gypsum Company* 83 F. Supp. 613 (D.C. Pa. 1947); *Kennedy v. U.S.* 115 F.2d 624 (CA-9, 1940).

Request for Additional Findings, Conclusion and Judgment

A. Radovan U.S. Patent 4.217,889 ('889)

The Findings of Fact and Conclusions of Law entered by this Court form a basis for additional findings as to the '889 patent relative to the improper prosecution of the infringement action based on this patent leading to a conclusion that this portion of the litigation is exceptional within the meaning of 35 USC 285 and an award of attorney's fees in favor of the defendant should be made, along with the corresponding amendments to the Judgment.

B. Becker U.S. Patent 4.643,733 ('733)

The Findings of Fact and Conclusions of Law with respect to Becker as to the validity of the patent show that the necessary investigation and due care required of a patent owner with regard to the validity of the patent was not entered into as certain admissions made by the patentee, Becker, formed the basis for the Court's invalidity and unenforceability decision and would render the case exceptional within the meaning of 35 USC 285 requiring an evaluation of the award of attorney's fees. In addition, the facts presented at trial with respect to the inequitable conduct are ripe for decision.

Mentor's Infringement Claim as to the '889 Patent is "Exceptional"

The enforcement of the Radovan et al '889 patent in this case is "exceptional" within the meaning of 35 USC 285 based on this Court's present Findings of Fact as to the issues

of infringement of the Radovan et al patent claims, namely, Findings Nos. 48 through 50. Finding No. 48 includes the recitation that "it is incredible that a patent owner could assert infringement of patent claims without revealing the application of the patent claims to a defendant's accused structures, long after commencing the litigation". In addition, Finding No. 50 establishes that Mentor did not provide any proof concerning their theory of infringement.

In addition to the aforementioned Findings of Fact, this Court's Conclusion of Law No. 15 further established that "Mentor presented no proofs of infringement of a properly interpreted patent claim". The *Fonar* citation in Conclusion of Law No. 15 clearly establishes that without a proper interpretation of the patent claims, no proof of infringement has been validly presented, and with no proper proofs, there has been a complete failure of the plaintiffs to meet their burden of proof on infringement and this matter should have been appreciated or known by the plaintiffs long prior to the trial. This is also supported by the Court's Finding No. 24 which essentially establishes the prosecution history estoppel governing the proper interpretation of the claims.

It should also not go unnoticed that the plaintiffs presented no rebuttal to the defendant's position on non-infringement and file wrapper estoppel at the trial and merely relied on their patent law expert's testimony based on an assumption of validity of the Radovan et al patent, as is evidenced by the Court's Conclusion of Law No. 15.

What is incredible is Mr. O'Neill's rebuttal closing argument on the last day of the trial. Mr. O'Neill made certain admissions to the Court concerning his agreement with the defendant's position that the Radovan et al patent claims require the tissue expander to have a substantially non-distensible base. He also agreed that there was prosecution history estoppel on this point, again agreeing with the Cox-Uphoff defense. The Mentor patent law expert saw it differently. Cox-Uphoff's witnesses established the fact that the

"Versafil" tissue expander had a distensible, non-shape retaining base. The Court's conclusions on infringement are supported by Mr. O'Neill's admissions.

Mr. O'Neill asked the jury to prove his case and experiment with the exhibits. Was this not an admission of the failure to meet the Mentor burden of proof on the infringement of Radovan et al? The answer is obviously, "Yes".

Mr. O'Neill's remarks included the question to the jury, "Why are we here?" (page 142, line 13, of the attached trial transcript). Now that the jury has been dismissed, we all know why we were there—Mentor's management wanted to make an example of little Cox-Uphoff Corporation to the industry. That was obviously the motive for Mentor's actions since the rushing through of the litigation did not take into consideration the required, detailed analysis of the infringement claims.

Counsel for defendant now asks, "Why did not Mentor admit, what Mr. O'Neill now admits, long before the trial?" The reason Cox-Uphoff was in trial should now be evident to all. Again, Mentor refused to accept the position that Mr. O'Neill admitted to at the end of the trial. Should Cox-Uphoff bear the expense of going through trial when they were right on their position prior thereto and Mentor refused to concede? The defendant submits that Mentor should be assessed the defendant's attorney's fees. Copies of certain pages from the trial transcript are attached hereto.

The aim of the Statute, 35 USC 285, with respect to awarding a prevailing accused infringer his attorney's fees is to "prevent a gross injustice"; *Revlon v. Carson Products Co.* 803 F.2d 676, 679, 231 USPQ 472, 473-474 (Fed. Cir. 1986). Prevailing accused infringers have been awarded their attorney's fees when there has been an inadequate consideration of the infringement claim prior to trial and during the trial. Scientifically informed persons could not

differ on the actual physical characteristics and functions of the "Versafil" expander. In this case no technical expert appeared on behalf of the plaintiffs. The Federal Circuit has so indicated in *Machinery Corp. of America v. Gullfiber A.B.* 774 F.2d 467, 473, 227 USPQ 368, 372 (Fed. Cir. 1985).

Defendant submits that the plaintiffs could not in good faith believe that the defendant's device infringed when properly interpreted patent claims are evaluated. Although the presumption of validity pursuant to 35 USC 282 attaches to a patent when granted, no similar presumption attaches to an allegation of infringement, and an accuser infringer cannot hide behind the cloak of a presumption solely involving infringement; see page 372 of 227 USPQ of *Machinery Corp.*, *Supra*, citing *Kaehni v. Diffraction Co., Inc.* 342 F. Supp. 523, 535, 173 USPQ 705, 714 (D. Md. 1972); *aff'd mem.*, 473 F.2d 908, 178 USPQ 321 (4th Cir.); *cert. den.* 414 U.S. 854 (1973). Under such circumstances courts have found that the litigation is exceptional, and the caption to this Court's Finding of Fact, "Caption C", on page 17, would readily lead to such a conclusion, along with the aforementioned Findings and Conclusion of Law, that this case is, in fact, exceptional; and the Court is respectfully requested to now make such a finding, along with a Conclusion of Law that the defendant is entitled to its attorney's fees with respect to the unnecessary defense to the claim of infringement based on the Radovan et al patent to prevent a gross injustice to the defendant Cox-Uphoff Corporation. It should not be overlooked that the cost of patent litigation these days is very high. Accordingly, an improperly brought infringement claim made against a small company (such as the defendant) may be a commercial weapon that cannot be fought back. Since the law requires that the Court make a specific finding of the exceptional circumstances as a prerequisite to awarding attorney's fees under 35 USC 285, such a request is deemed in order in this case and consistent with the Court's prior Findings and

Conclusions of Law; *Stevenson v. Sears, Roebuck & Co.* 713 F.2d 705, 712-713, 218 USPQ 969, 975 (Fed. Cir. 1983).

Similarly, defendant requests that with the entered finding of exceptional circumstances that a Conclusion of Law be added by the Court indicating that the defendant is entitled to its attorney's fees for defending against the claim of infringement of the Radovan et al '889 patent.

The Assertion of the Becker Patent 4,643,733 is "Exceptional"

The defendant submits that this litigation is exceptional with respect to the Becker patent within the meaning of 35 USC 285 on at least three different grounds, taken individually and/or collectively. These grounds include (1) the inequitable conduct of the applicant Becker in procuring his patent from the U.S. Patent and Trademark Office, (2) the invalidity under 35 USC 102, based on Dr. Becker's own publication admitting prior use more than one year before the filing date of the Becker patent application, and (3) the invalidity under 35 USC 103, based on Dr. Becker's own publications, not disclosed to the Patent Office, which established the simple substitution of a known prior art device into the basic admittedly known implant to achieve "delayed filling".

Defendant submits that although the Court did not enter any Findings of Fact and Conclusions of Law on the infringement issues relative to the Becker patent, obviously, in view of the invalidity of the asserted patent claims, nevertheless, it should be noted that the plaintiffs resorted to the same type of erroneous infringement analysis through their patent law expert witness that they put forth with regard to the Radovan et al patent. The requirement for defending against the infringement claim should also be considered in the overall view of the exceptional nature of the plaintiff's litigation. It will be recalled that two distinctly different designs of the defendant's "RDL-Xpand" (reverse double lumen) mammary implant were charged to infringe. Plain-

tiffs' patent law expert attempted to equate the two designs on a broad basis for infringement purposes without reference to the prior Heyer-Schulte inflatable implant.

Inequitable Conduct—Becker

Defendant submits that the Findings of Fact established by this Court support the defendant's claim that the Becker patent was obtained by inequitable conduct. The elements for evaluating inequitable conduct before the Patent and Trademark Office has been established by the decision of the Court of Appeals for the Federal Circuit in *J. P. Stevens & Co. v. LexTex, Ltd.* 747 F.2d 1553, 1559, 223 USPQ 1089, 1092 (Fed. Cir. 1984). The *J. P. Stevens* tests were refined in *A. B. Dick Company v. Burroughs Corp.* 798 F.2d 1392, 230 USPQ 853, 854 (Fed. Cir. 1986). The *J. P. Stevens* decision sets out the starting point is the Patent Office Rule of Practice 1.56, 37 C.F.R. 1.56, and that the materiality of omitted or false information and intent of the actor must be balanced and considered with different weights given, depending on the materiality of withheld information or erroneous information submitted to the Patent Office. The matter of intent, only, was recently clarified by an *in banc* decision of the Federal Circuit in *Kingsdown Medical v. Hollister, Inc.* 9 USPQ 2d 1384 (Fed. Cir. Dec. 21, 1988), *Supra*. This Federal Circuit decision indicates that the element of intent must be evaluated from the standpoint that the involved conduct must be viewed in light of all the evidence to require a finding of intent to deceive. This, of course, is in respect to the basic elements defined in the *J. P. Stevens, Supra*, decision concerning materiality and intent and the balancing required in coming to a conclusion, as a matter of law. The Federal Circuit has recognized that the required balancing requires judicial discretion be brought to bear and the District Court judge should decide it and not a jury; *American Hoist & Derrick Co. v. Sowa & Sons, Inc.* 725 F.2d 1350, 1364, 220 USPQ 763, 774 (Fed. Cir. 1984).

Defendant submits that Findings of Facts Nos. 52, 53, 54, 56, 57, 59, 60, 62, 65, 66, 67, 68, 69 and 73 establish the exceptional circumstances with respect to Dr. Becker's conduct before the Patent Office, leading to a legal conclusion that he obtained his patent on the basis of inequitable conduct.

A. Application Changed After Execution

Unlike the usual situation, the starting point in this case is a portion of Patent Office Rule of Practice 37 C.F.R. 1.56 that relates to the patent application and declaration as filed in the Patent Office by Dr. Becker. The Becker patent application as filed in the Patent Office on April 4, 1983, was marked up, altered and amended after execution of the declaration, contrary to 37 C.F.R. 1.56(c)(4); see Finding No. 52. This Finding establishes the significance of Becker's alterations to his patent application after execution of the declaration and as filed in the Patent Office. The plaintiffs, including Dr. Becker, have continuously insisted that the "delayed filling" implant developed by Dr. Becker was a substantial advance in the art, all while recognizing that Dr. Radovan had disclosed this "delayed filling" feature prior to Becker; see Findings Nos. 52 and 54. In addition, it will be noted that the term "subcutaneous expander" was utilized in the publications of Dr. Radovan et al and in the Heyer-Schulte publications known to Dr. Becker. Nevertheless, in originally claiming the alleged Becker improvement over the prior art, Becker's counsel was not successful since all of the original patent application claims were identically descriptive of the device disclosed in the Radovan '889 patent and the Radovan publications; see Finding of Fact No. 57. Accordingly, despite the admissions of Dr. Becker concerning Dr. Radovan et al's prior work and the Heyer-Schulte prior work, he claimed the Radovan et al invention when he submitted his altered application to the Patent and Trademark Office in order to bring out, among other things, "delayed filling".

The defendant submits that this is one factor in evaluating the Becker conduct before the Patent Office and should be placed on the pans of the balance for legally evaluating Dr. Becker's conduct before the Patent Office. The alterations per se are considered serious acts of misconduct by the Patent and Trademark Office and have been considered so for quite a few years, as evidenced by the decision of the Commissioner of Patents in 1959 in *Wainer v. Ervin* 122 USPQ 608; also note Manual of Patent Examining Procedure, 5th ed. rev. May, 1988, ¶2005, pages 2000-10 through 2000-12.

B. Failure to Disclose Material Information

The other aspect of Patent Office Rule 1.56 is the "duty" of applicant and his counsel to disclose material information to the patent examiner, as represented in the Courts Findings Nos. 53 and 54. It is seen that Dr. Becker was fully advised by his counsel concerning his duty and that certain disclosures as to *material* information was made to the Patent Office as represented in Finding No. 54; i.e., page 21, lines 9-13 of Finding No. 54. Dr. Becker, however, did not disclose all the material information of which he was aware at the time of filing his patent application and on or about that time. These material publications included admissions by Dr. Becker as to what he, in fact, had done and which was confirmed by him at the trial. These undisclosed, material references are set out in this Court's Finding of Fact No. 65, along with Dr. Becker's admissions. In addition to his own publications, the exclusive licensee, Mentor, made certain representations concerning material prior art to the Federal Drug Administration with respect to the prior activities of others, as evidenced by this Court's Findings Nos. 66 and 67. This Court's Finding No. 68 establishes Dr. Becker's knowledge of the Birnbaum/Olsen publication identified in Finding No. 67 and the reasons that it was not submitted to the patent examiner by Dr. Becker. The Birnbaum/Olsen publication was directly contrary to the Declaration of one Dr. Caffee filed in the Patent Office on behalf of Dr. Becker,

as indicated in Finding No. 79. This publication is material since it also describes the use of a single implant that is periodically expanded and left in the body permanently after expansion.

The materiality of this undisclosed information is clear, including the fact that a reasonable examiner would have considered this undisclosed information important in determining to grant a patent. Focusing on this alone, the Examiner would have undoubtedly refused to allow the Becker patent application claims.

If we assume that Dr. Becker's analysis of the Lake patent as evidenced by Finding No. 68, that it discloses a single implant that functioned as a tissue expander and a permanent implant, then the submission of Dr. Caffee's Declaration, Finding No. 60, by Becker was unnecessary and mislead the patent examiner as to the prior art.

Another fact to be considered is represented by Finding No. 69 that Dr. Becker was not candid with the patent examiner concerning the leakage problem of a single lumen implant of which he was personally aware and which was well known in the industry at the time. Dr. Becker did not disclose that the solution to the leakage problem could be through the use of a different construction, as discussed with Cox-Uphoff's president and evidenced by the Court's Finding No. 70. These matters are all, beyond question, material information that the examiner should have considered prior to allowing the Becker patent application.

Furthermore, the patent examiner did not have Dr. Becker's publications, including Dr. Becker's admissions, before him wherein Dr. Becker admitted that he made a simple substitution of prior art devices and is in Finding No. 65. In view of the examiner's initial examination of and position on Dr. Becker's patent application claims, if the examiner had Becker's admissions before him, it would have clearly established that the examiner's initial rejection was

correct and the application would not have issued as a patent. This is comprehended by the Court's Finding No. 58. In any event, the admissions made by Dr. Becker in his publications were not before the Patent Office and also should have led him to understand that the allowed, amended claims did not distinguish over the prior art and which amended claims appear in the patent in suit and have been asserted against the defendant.

The only basis for distinguishing over the Radovan et al '889 patent related to the characteristic of the prosthesis described in the claims which were obviously true of the prior art Heyer-Schulte implant so that Dr. Becker should have known that the amendatory material was not original with him and could not distinguish over known prior art, as evidenced by Findings Nos. 71 and 72.

Defendant submits the above clearly establishes the withholding of *material* information that should have been evaluated by the examiner, as a whole, prior to completing his examination. It was also clear that the examiner would have rejected the Becker application had he had all the undisclosed information before him.

There can be no issue that Dr. Becker's admissions are material to the examination of his patent application. A determination of inequitable conduct will not be avoided if knowledge of materiality or gross negligence greatly outweighs the lack of deceptive intent, as the facts establish herein; *A. B. Dick Co. v. Burroughs Corp.* 798 F.2d 1392, 1398, 230 USPQ 849, 854 (Fed. Cir. 1986). *Supra*.

As to completing the analysis on intent, the failure of Dr. Becker to disclose material information establishes that he was grossly negligent, if not intentionally deceitful, as a natural consequence of his non-disclosures.

The defendant submits that the materiality of the undisclosed information weighs most heavily in balancing Dr. Becker's conduct before the PTO, particularly in view of the

wealth of undisclosed information, including the disclosures to the Federal Drug Administration. In balance, the facts should cause the Court to conclude that the Becker patent was procured by inequitable conduct.

Prior Use—35 USC 102

This Court has concluded that Dr. Becker's publication in April, 1984, Exhibit 223, establishes Becker's admission of a public use of the Becker claimed device more than one year before the filing date of the Becker patent application; see Conclusion of Law No. 21. This Conclusion of Law is based on the Court's Finding No. 80.

The Court's attention is also directed to Mentor's Answers to the Defendants' Interrogatories and Requests for Production of Documents which bear on the issue of prior sale and Dr. Becker's publication that is recited in Finding No. 80. In the Plaintiffs' Answer to Defendants' Interrogatory No. 6 (Exhibit 271) and the Supplemental Answer thereto, Exhibit 270, references are made to Becker's April 19, 1984, publication and references the updating of the publication by Dr. Becker. Yet, in responding to the Request for Documents, Exhibit 272, Requests 2, 3 and 4, evidence Mentor's lack of production of documents relating to conception, reduction to practice, of both patents in suit or documents supporting the first public use or first offer for sale or first publication. No document was ever produced at any time to support the allegations of the Answer to Interrogatory No. 6 that the publication was updated, or that would contradict the clear import of the statements made in Dr. Becker's own publication referenced in the Answer. Accordingly, no proofs were established that the date of first use was other than indicated by Dr. Becker in his own publication, and this admission of prior use establishes the invalidity of the Becker patent claims under 35 USC 102(b) beyond doubt.

In a factual situation that is on "all fours" with respect to the facts of this case, the Federal Circuit has affirmed a

conclusion of a prior sale (identical to prior use) under 35 USC 102 based on an *admission* by the patent owner and the fact that the patent owner brought suit on the patent despite its knowledge of the prior sales; *Interpart Corp. v. Imos Italia* 777 F.2d 678, 686, 228 USPQ 124, 130 (Fed. Cir. 1985).

The Federal Circuit in *Interpart*, *Supra*, also affirmed the District Court's conclusion that, on the basis of the admission of such prior activities, the finding that the case was an exceptional one for the purposes of attorney's fees under 35 USC 285, was proper and is also proper in this litigation. The defendant is entitled to an award of attorney's fees on this basis, as well, in this case.

Similarly, the issue of inequitable conduct, failure to disclose a party's own publications and commercial devices re 35 USC 102 was treated in *A. B. Chance Co. v. RTE Corp.* 854 F.2d 1307, 7 USPQ 2d 1881 (Fed. Cir. 1988).

Invalidity Under 35 USC 103

Along with the Court's Findings discussed hereinabove, a number of them also relate to what the defendant submits was a clear case of invalidity of the Becker patent claims based on Dr. Becker's pre-trial admissions and the submission of claims that were identical to the disclosures in the admitted prior art Radovan et al patent. These facts are evidenced by Findings Nos. 57, 58, 62, 72, 73, 74, 76, 77, 79 and Conclusion of Law 18. Defendant submits that for the purpose of an "exceptional" case evaluation under 35 USC 285, these facts should be evaluated, along with the fact that the plaintiffs merely relied on the presumption of patent validity under 35 USC 282 and presented no rebuttal evidence concerning the invalidity under 35 USC 103. The rejection by the patent examiner of the patent application claims was based on 35 USC 102 which established the *identity* with the Radovan et al patent disclosure; see Finding No. 61.

The defendant in relying on Finding No. 62 submits that a good faith evaluation of the claimed subject matter in light

of the record before the Patent Office, alone, should have established to Mentor, prior to trial, the invalidity of the Becker patent in suit.

It is very important to note for the purposes of this Motion that the amendatory material included in Finding No. 62 not only is descriptive of the prior art Heyer-Schulte implant known to Becker (as well as other prior art implants known to Becker)², but also the fact that the "rigid base" characterization of the Radovan et al patented tissue expander argued by Becker's counsel before the PTO, was not Mentor's position at the trial. Mentor, in attempting to stretch the '889 patent claims, did not consider the claims were restricted to a rigid base. If this position were correct (which this Court found it was not), the amended Becker patent application claims would be descriptive of the Radovan prior art under 35 USC 102 in the identical manner the examiner found with respect to the original Becker patent application claims. Stated differently, the amended and unamended claims are identically descriptive of the prior art. This erroneous position should have been known to Mentor not only before the trial, but also before the charge of infringement made against the defendant and the commencement of this litigation as these matters were all a part of the public record.

Also, if it is considered the Radovan known prior art is not restricted to a substantially rigid base portion, but is flexible, the Radovan teachings were misrepresented to the PTO and for that reason, as well, the Becker patent was obtained by inequitable conduct.

The Court's Finding No. 77 established the "lapse on the part of the Examiner" in allowing the Becker patent

² The Radovan et al patent, acknowledged by Dr. Becker before the Patent and Trademark Office to be prior art, also describes the prior art tissue expander of Dr. Neumann which was a balloon flexible in all directions; see column 1, lines 43-55, of the '889 patent.

application claims. Apparently, there was a “lapse” on the part of Dr. Becker in not recognizing that the simple amendment to his patent application claims could not possibly distinguish over the prior art in a patentable sense. The law is clear that when a patent applicant commits fraud, or was so grossly negligent as to support an inference of fraud or inequitable conduct, “lapse” on the part of the examiner does not excuse the applicant’s conduct; *KangaROOS U.S.A., Inc. v. Caldor, Inc.*, 778 F.2d 1571, 1576, 228 USPQ 32, 35 (Fed. Cir. 1985). This establishes, as well, the “exceptional” nature of this litigation.

In addition, with respect to Mentor’s knowledge of the prior art as represented by the FDA submission, including the Birnbaum/Olsen publication, it should have been readily apparent to Mentor’s counsel and those skilled in the art that the two-step procedure was not, in fact, novel and unique to Dr. Becker and that the mere substitution of the prior art reservoir or syringe for the prior art port of Radovan would have been readily accomplished by anyone skilled in the art. It was left to Cox-Uphoff to prove these facts at trial and to establish the clear invalidity of the Becker patent in the interest of the public.

The above comments apply to the prior art of record in the Becker patent application; however, the uncited prior art should also lead Mentor to conclude the Becker patent claims were invalid – “obviously”. This Court’s Finding No. 78 with respect to the uncited Berson patent 4,246,893 establishes the minor difference between the Becker patent claims and the prior art not uncovered by the patent examiner. The Radovan et al prior teachings disclose the detachable fill tube at the prosthesis which is not in the Berson ’893 patent. Yet, this prior art was ignored by Mentor in pushing forward with this litigation.

Radovan-Becker Patents

The above analysis was applied to the Radovan et al and the Becker patents individually. Defendant submits that the

Court should also consider the overall view of the patent litigation based on these two patents and the conduct of Mentor with respect to the pre-trial proceedings, the failure to properly evaluate the infringement issues and the validity of the Becker patent, as well as the detailed grounds submitted hereinabove concerning each of these patents, so that the Court can readily conclude that this is an "exceptional" case and that attorney's fees should be awarded.

In the event the Court agrees that attorney's fees should be awarded, an opportunity for the defendant's counsel to present the evidence to support the specific amounts with regard to attorney's fees is respectfully requested, and it is respectfully requested that this Court reserve jurisdiction of this matter for that purpose.

AMENDMENT OF JUDGMENT AND FINDINGS OF FACT

The Judgment as entered at the present time includes an obvious error that renders it inconsistent with the Court's Conclusions of Law. Paragraph 9(a) should be amended to conform with Paragraph 3, namely, that the '889 patent is not invalid.

Defendant also requests amendment of Finding of Fact No. 57 so as to refer back to Finding No. 51 rather than Finding No. 55.

The defendant is including under separate cover proposed additional Findings of Fact and Conclusions of Law for the Court's consideration.

MOTION FOR NEW TRIAL—Rule 50(b)

The defendant previously moved for a judgment notwithstanding the verdict, and in the alternative, for a new trial pursuant to Federal Rule of Civil Procedure 50(b). This Court granted the motion for J.N.O.V., but did not rule on

the motion for a new trial. The defendant now requests a conditional ruling on the motion for a new trial for the purposes of appeal be entered at the present time.

Defendant submits that the Court must pass on the motion for new trial despite the fact that the motion for J.N.O.V. has been granted; 5A Moore's Federal Practice, Paragraphs 50.13[1] and 50.14, pages 50-94 through 50-107, including cases cited therein.

CONCLUSION

The defendant's Motion should be granted, the Findings of Fact and Conclusions of Law and Judgment should be amended, and the defendant should be awarded its attorney's fees to avoid a gross injustice. A conditional ruling granting a new trial should be entered.

Respectfully submitted,

EDWARD J. DaRIN, INC.

Date: 2/17/89

By EDWARD J. DaRIN
Edward J. DaRin
Attorney for Defendant
Cox-Uphoff Corporation

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

HONORABLE JESSE W. CURTIS, SENIOR DISTRICT
JUDGE PRESIDING

MENTOR CORPORATION, *et al.*,

Plaintiffs,

VS.

COX-UPHOFF CORPORATION, *et al.*,

Defendants.

} CV 87-5611-JWC (ER)

REPORTER'S TRANSCRIPT OF PROCEEDINGS
LOS ANGELES, CALIFORNIA
THURSDAY, SEPTEMBER 22, 1988

SUSAN A. LEE, CSR 2800, CM, RPR
OFFICIAL COURT REPORTER
435 UNITED STATES COURTHOUSE
312 NORTH SPRING STREET
LOS ANGELES, CALIFORNIA 90012
(213) 626-6353

PATENT OFFICE.

THANK YOU.

MR. O'NEILL: MY TURN, JUDGE?

THE COURT: YOUR TURN FOR ABOUT 10 MINUTES.

MR. O'NEILL: 12 MINUTES?

THE COURT: 11.

COURTROOM: (LAUGHTER.)

REBUTTAL +

MR. O'NEILL: LET ME DEAL WITH RADOVAN QUICKLY AND THIS WHOLE ISSUE OF ESTOPPEL AND DR. HARTLEY'S PATENT. AND I'LL DO EXACTLY WHAT I SAID COUPLE OF MINUTES AGO. (REFERRING TO EXHIBIT.)

I AGREE WITH HIM (POINTS TO DEFENSE COUNSEL) THAT DR. RADOVAN'S PATENT REQUIRES THAT THE BOTTOM BE SUBSTANTIALLY NONDISTENSIBLE. I AGREE.

AND THE REASON IT REQUIRES THAT IT BE SUBSTANTIALLY NONDISTENSIBLE IS BECAUSE OF THE PROSECUTION HISTORY INTO THE PATENT OFFICE AND DR. HARTLEY'S PATENT, WHICH MR. FRINKS EXAMINED. AND THE PRIOR ART. I AGREE.

AND THE CLAIMS WERE LIMITED SO THAT THE BOTTOM WOULD BE SUBSTANTIALLY NONDISTENSIBLE: SUBSTANTIALLY NONDISTENSIBLE. AND THE PATENT TEACHES DIFFERING DEGREES. I AGREE WITH THEM.

THE QUESTION IS: IS THE BOTTOM OF THE DEVICE SUBSTANTIALLY NONDISTENSIBLE? I

AGREE WITH THEM ON THE LAW. I AGREE WITH THEM ON THE PROSECUTION HISTORY.

GO BACK AND SEE IF YOU CAN DISTEND THE BASE. AS HARD AS YOU CAN. SEE IF THE BASE WILL DISTEND.

WHEN IT GOES IN THE BODY, THE BOTTOM FLATTENS OUT. WHY DOES IT FLATTEN OUT? IT FLATTENS OUT SO THAT THE FORCES ARE DISTRIBUTED AROUND THE BASE.

AND IF YOU FILL IT UP ALL THE WAY—SEE, THEY DIDN'T FILL IT UP ALL THE WAY. WE'VE BEEN THROUGH THAT. BUT, YOU KNOW, GO BACK THERE AND TAKE THIS HUMMER (HOLDING SYRINGE) AND FILL THEM UP.

AND, YOU KNOW, DON'T ACCEPT THE LAWYER'S ARGUMENTS ON THE THING. FIGURE IT OUT YOURSELF. WE'LL RISE OR FALL ON HOW YOU FIGURE IT OUT.

BUT I AGREE WITH THEM: IT REQUIRES A SUBSTANTIALLY NONSIMILAR BASE, AND HE TEACHES IN THE PATENT DIFFERING DEGREES OF DISTENSIBILITY.

I COULD BREAK THIS THING AND GO TO JAIL FOR BREAKING A COURT EXHIBIT. (SQUEEZING EXHIBIT.)

I AGREE. OKAY? SO THAT'S IT. THE INFRINGEMENT OF THE RADOVAN PATENT IS A RELATIVELY EASY ISSUE.

AND WE GOT THE ARGUMENT AGAIN ABOUT THE INITIALING. WHEN I GOT ON THORNTON AND—I SHOULDN'T SAY "WHEN I GOT ON."

WHEN I WAS CROSS-EXAMINING MR. THORNTON, I SAID, "MR. THORNTON, IS THE FACT THAT

HE CHANGED IT MEANT—WERE YOU THE TELLING THE JURY THAT THE PATENT'S INVALID?"

AND HE SAID, "NO, I WASN'T."

WENT RIGHT AT IT, DIRECTLY. BUT THEY BRING THE AGRUMENT UP AGAIN. IT'S MUDSLINGING.

BERSON: HE SAYS, "TAKE A LOOK AT THE BERSON PATENT." HERE'S THE FIRST IMAGE OF THE BERSON PATENT. OKAY?

THE PROSTHESIS IS IN THIS GOOD-LOOKING GUY'S STOMACH. IT'S IN HIS STOMACH. IT ISN'T USED FOR BREAST EXPANSION, IT ISN'T USED FOR SKIN EXPANSION; IT'S IN HIS STOMACH.

WE JUST HEARD THAT DR. BECKER IN HIS PATENT APPLICATION DID NOT CITE—AND HE JUST SPECIFICALLY SAID, "HE DID NOT CITE A REVERSE DOUBLE LUMEN TO THE PATENT EXAMINER."

THIS IS THE KONECKE PATENT: (DISPLAYS TO JURY.) THE KONECKE PATENT IS A REVERSE DOUBLE LUMEN. IT WAS CITED TO THE PATENT EXAMINER.

THE RADOVAN PATENT WAS CITED TO THE PATENT EXAMINER. THE HEYER-SCHULTE BREAST IMPLANTS AND THE HEYER-SCHULTE SKIN EXPANDER WERE CITED TO THE PATENT EXAMINER. THE PATENT EXAMINER HAD ALL OF THIS STUFF.

REVERSE DOUBLE LUMEN: THE REVERSE DOUBLE LUMEN TECHNOLOGY, THIS KIND OF REVERSE DOUBLE LUMEN IS BACK IN 1973, BEFORE COX-UPHOFF WAS EVER BEGUN. COX-UPHOFF DIDN'T INVENT REVERSE DOUBLE LUMEN TECHNOLOGY; ERNEST WILHELM KONECKE FROM WET-

TMAR, GERMANY, CAME UP WITH THE FIRST REVERSE DOUBLE LUMEN PATENT. HERE IT IS. IT WAS CITED TO THE EXAMINER.

NOW WE GET TO THE BIG SMEAR. YOU KNOW, "MENTOR KNEW ABOUT ALL OF THIS TECHNOLOGY IN THE 510(K) FILING, AND SO THEY SHOULD HAVE GONE TO THE EXAMINER TO TELL THE EXAMINER ABOUT EVERY SINGLE PATENT THAT THEY KNEW"?

MR. WESTMAN TESTIFIED AS TO WHAT THE OBLIGATION OF THE APPLICANT IS. THE APPLICANT'S OBLIGATION IS NOT TO CITE EVERY BIT OF PRIOR ART THAT HE KNOWS. THE APPLICANT'S OBLIGATION IS TO GO TO THE EXAMINER AND CITE WHAT IN HIS VIEW'S THE BEST, MOST PERTINENT ART; THE BEST STUFF. SO THAT'S THE APPLICANT'S OBLIGATION.

AND WHAT DID BECKER CITE TO THE EXAMINER? RADOVAN, A REVERSE DOUBLE LUMEN PROSTHESIS; LAKE, WHICH IS THE SAME AS BIRNBAUM AND OLSON. HE CITED THE BEST STUFF. AND THERE'S NO EVIDENCE THAT HE TRIED TO HIDE ANYTHING OR TRICK ANYBODY.

THEN THERE'S THE ARGUMENT, "WELL, HE DIDN'T TELL THE EXAMINER ABOUT LEAKY SALINE LUMENS."

THEY'VE MADE SALINE LUMENS FROM 1971 TO THE PRESENT DAY. AND THEY'RE GOING TO GO OUT WITH ONE NOW.

DOES THE PATENT COVER A DOUBLE LUMEN? I'M NOT JUST RELYING ON THE PARAGRAPH IN FRONT OF THE PATENT CLAIM. I'M RELYING ON THE CLAIM ITSELF. WHAT DOES THE CLAIM SAY?

GO BACK THERE WITH THE CLAIM BOOK AND APPLY THE CLAIM. AND THEN WANDER AROUND

THAT PATENT. LET ME GIVE YOU THE COLUMN AND THE LINE NUMBER. COLUMN 6, LINE 11:

"IN ADDITION, THE DEVICE OF THIS INVENTION IS USEFUL IN OTHER IMPLANTS WHERE"—SHE THINKS I TALK TOO FAST (INDICATING REPORTER)—"WHERE DELAYED EXPANSION IS DESIRABLE. AS IN MANY BREAST IMPLANTS, IT MAY BE THAT THE IMPLANT SHOULD NOT BE EXPANDED UNTIL THE WOUND HAS HAD A CHANCE TO HEAL."

HMM? AND HE CITED TO THE EXAMINER A REVERSE DOUBLE LUMEN. AND THEY DRAFTED THE CLAIM SO THE CLAIM WOULD COVER THE INVENTION.

THE CLAIMS COVER, BY THEIR WORDS: THE DEVICES DO SUBSTANTIALLY THE SAME THING IN SUBSTANTIALLY THE SAME WAY TO ACCOMPLISH SUBSTANTIALLY THE SAME RESULTS AS THE TWO PATENTS.

AND WE HAVE GOTTEN A TYPICAL COPIER'S DEFENSE: "I DIDN'T HIT HER. BUT IF I DID, SHE MADE ME DO IT. AND IN ANY CASE, SHE WASN'T DAMAGED."

WHO COPIED WHOSE HERE? I MEAN, WHY ARE WE HERE? ARE WE HERE—ARE THEY SUING ANYBODY FOR INFRINGING THEIR PATENTS? WHO COPIED WHAT?

THEY "DIDN'T HIT HER."

THEY'VE GOT TO HAVE EVERY DEFENSE. IF ANY ONE SINGLE DEFENSE WAS GOOD, THAT'S ALL YOU'D HEAR ABOUT. BUT YOU THROW IT UP ON THE WALL. CONFUSE THE JURY, AND SEE IF IT STICKS. IT DOESN'T WORK.

DR. BECKER'S A FINE MAN, DR. RADOVAN WAS A FINE MAN; THEY HELPED PEOPLE. AND COX-UPHOFF COPIED THE DEVICES.

THANK YOU, JUDGE.

FINAL INSTRUCTIONS +

THE COURT: LADIES AND GENTLEMEN, THE VERDICT WHICH

THE COURT: YES.

MR. DaRIN: IT'S BEEN A WHILE SINCE I LOOKED AT THESE SPECIAL INTERROGATORIES. I WAS TRYING TO RECALL IF THERE WAS ONE THERE WITH REGARD TO INEQUITABLE CONDUCT.

MR. O'NEILL: THERE IS ONE.

THE COURT: I THOUGHT THERE WAS.

MR. O'NEILL: THERE IS ONE.

MR. DaRIN: I JUST WANTED TO CHECK. THANK YOU.

THE COURT: VERY WELL. COUNSEL WILL LEAVE YOUR TELEPHONE NUMBERS WITH THE CLERK SO WE CAN REACH YOU.

MR. O'NEILL: THANK YOU VERY MUCH, JUDGE. IT WAS FUN.

THE COURT: WE'LL MISS YOU. HOWEVER, WE MAY PROCEED FASTER WITH YOU IN MINNEAPOLIS.

COURTROOM: (LAUGHTER.)

THE COURT: ALL RIGHT, GENTLEMEN. IT'S BEEN AN INTERESTING CASE. I'VE ENJOYED LISTENING TO BOTH OF YOU.

MR. DaRIN: THANK YOU, YOUR HONOR.

THE COURT: WE STAND ADJOURNED.

(PROCEEDINGS ADJOURNED TILL SEPTEMBER
23, 1988.)

I CERTIFY THAT THE FOREGOING IS A CORRECT
TRANSCRIPT FROM THE RECORD OF PROCEEDINGS
IN THE ABOVE-ENTITLED MATTER.

SUSAN A. LEE

DATED: February 15, 1989

SUSAN A. LEE, CSR 2800,

CM, RPR OFFICIAL COURT REPORTER

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of DEFENDANT'S MOTION TO AMEND THE FINDINGS OF FACT, CONCLUSIONS OF LAW, AND JUDGMENT AND FOR ATTORNEY'S FEES; MEMORANDUM OF POINTS AND AUTHORITIES was sent, postage prepaid, by depositing it with the United States Postal Service as first class mail, addressed to the following counsel for plaintiffs, this 17th day of March, 1989,

Darla Anderson, Esq.
Mentor Corporation
600 Pine Avenue
Goleta, CA 93114

and to

Faegre & Benson
2200 Norwest Center
90 South Seventh Street
Minneapolis, MN 55402-3901
ATTN: Alan Anderson, Esq.

by Federal Express, this 17th day of March, 1989.

EDWARD J. DaRIN

Edward J. DaRin

28 USC § 2071. Rule-making Power Generally

(a) The Supreme Court and all courts established by Act of Congress may from time to time prescribe rules for the conduct of their business. Such rules shall be consistent with Acts of Congress and rules of practice and procedure prescribed under section 2072 of this title.

(b) Any rule prescribed by a court, other than the Supreme Court, under subsection (a) shall be prescribed only after giving appropriate public notice and an opportunity for comment. Such rule shall take effect upon the date specified by the prescribing court and shall have such effect on pending proceedings as the prescribing court may order.

(c)(1) A rule of a district court prescribed under subsection (a) shall remain in effect unless modified or abrogated by the judicial council of the relevant circuit.

(2) Any other rule prescribed by a court other than the Supreme Court under subsection (a) shall remain in effect unless modified or abrogated by the Judicial Conference.

(d) Copies of rules prescribed under subsection (a) by a district court shall be furnished to the judicial council, and copies of all rules prescribed by a court other than the Supreme Court under subsection (a) shall be furnished to the Director of the Administrative Office of the United States Courts and made available to the public.

(e) If the prescribing court determines that there is an immediate need for a rule, such court may proceed under this section without public notice and opportunity for comment, but such court shall promptly thereafter afford such notice and opportunity for comment.

(f) No rule may be prescribed by a district court other than under this section.

28 USC § 2072. Rules of Procedure And Evidence; Power To Prescribe

(a) The Supreme Court shall have the power to prescribe general rules of practice and procedure and rules of evidence for cases in the United States district courts (including proceedings before magistrates thereof) and courts of appeals.

(b) Such rules shall not abridge, enlarge or modify any substantive right. All laws in conflict with such rules shall be of no further force or effect after such rules have taken effect.

Rule 50. Motion for a Directed Verdict and for Judgment Notwithstanding the Verdict

(b) Motion for Judgment Notwithstanding the Verdict.

Whenever a motion for a directed verdict made at the close of all the evidence is denied or for any reason is not granted, the court is deemed to have submitted the action to the jury subject to a later determination of the legal questions raised by the motion. Not later than 10 days after entry of judgment, a party who has moved for a directed verdict may move to have the verdict and any judgment entered thereon set aside and to have judgment entered in accordance with the party's motion for a directed verdict; or if a verdict was not returned such party, within 10 days after the jury has been discharged, may move for judgment in accordance with the party's motion for a directed verdict. A motion for a new trial may be joined with this motion, or a new trial may be prayed for in the alternative. If a verdict was returned the court may allow the judgment to stand or may reopen the judgment and either order a new trial or direct the entry of judgment as if the requested verdict had been directed. If no verdict was returned the court may direct the entry of judgment as if the requested verdict had been directed or may order a new trial.

(c) Same: Conditional Rulings on Grant of Motion.

(1) If the motion for judgment notwithstanding the verdict, provided for in subdivision (b) of this rule, is granted, the court shall also rule on the motion for a new trial, if any, by determining whether it should be granted if the judgment is thereafter vacated or reversed, and shall specify the grounds for granting or denying the motion for the new trial. If the motion for a new trial is thus conditionally granted, the order thereon does not affect the finality of the judgment. In case the motion for a new trial has been conditionally granted and the judgment is reversed on appeal, the new trial shall proceed unless the appellate court has otherwise ordered. In case the motion for a new trial has been conditionally denied, the appellee on appeal may assert error in that denial; and if the judgment is reversed on appeal, subsequent proceedings shall be in accordance with the order of the appellate court.

(2) The party whose verdict has been set aside on motion for judgment notwithstanding the verdict may serve a motion for a new trial pursuant to Rule 59 not later than 10 days after entry of the judgment notwithstanding the verdict.

Rule 59. New Trials; Amendment of Judgments

(b) Time for Motion.

A motion for a new trial shall be served not later than 10 days after the entry of the judgment.

